

AMENDMENT TO H.R. 1
OFFERED BY MR. RANGEL OF NEW YORK AND
MR. DINGELL OF MICHIGAN

**(Amendment is to Medicare Prescription Drug and
Modernization Act of 2003)**

Strike all after the enacting clause and insert the
following:

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
2 **CURITY ACT; REFERENCES TO BIPA AND**
3 **SECRETARY; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the “Medi-
5 care Prescription Drug and Modernization Act of 2003”.

6 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
7 otherwise specifically provided, whenever in this Act an amend-
8 ment is expressed in terms of an amendment to or repeal of
9 a section or other provision, the reference shall be considered
10 to be made to that section or other provision of the Social Se-
11 curity Act.

12 (c) BIPA; SECRETARY.—In this Act:

13 (1) BIPA.—The term “BIPA” means the Medicare,
14 Medicaid, and SCHIP Benefits Improvement and Protec-
15 tion Act of 2000, as enacted into law by section 1(a)(6) of
16 Public Law 106–554.

17 (2) SECRETARY.—The term “Secretary” means the
18 Secretary of Health and Human Services.

19 (d) TABLE OF CONTENTS.—The table of contents of this
20 Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA
and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION MEDICINE BENEFIT

Sec. 101. Voluntary medicare outpatient prescription medicine program.

“PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED
AND DISABLED

“Sec. 1859. Medicare outpatient prescription medicine benefit.

“Sec. 1859A. Negotiating fair prices with pharmaceutical manufacturers.

“Sec. 1859B. Contract authority.



- “Sec. 1859C. Eligibility; voluntary enrollment; coverage.
- “Sec. 1859D. Provision of, and entitlement to, benefits.
- “Sec. 1859E. Administration; quality assurance.
- “Sec. 1859F. Federal Medicare Prescription Medicine Trust Fund.
- “Sec. 1859G. Compensation for employers covering retiree medicine costs.
- “Sec. 1859H. Medicare Prescription Medicine Advisory Committee.
- Sec. 102. Provision of medicare outpatient prescription medicine coverage under the Medicare+Choice program.
- Sec. 103. Medigap revisions.
- Sec. 104. Transitional assistance for low income beneficiaries.
- Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).
- Sec. 106. State Pharmaceutical Assistance Transition Commission.

TITLE II—MEDICARE+CHOICE

- Sec. 201. Medicare+choice improvements.
- Sec. 202. Making permanent change in Medicare+Choice reporting deadlines and annual, coordinated election period.
- Sec. 203. Specialized Medicare+Choice plans for special needs beneficiaries.
- Sec. 204. Medicare MSAs.
- Sec. 205. Extension of reasonable cost contracts.
- Sec. 206. Extension of municipal health service demonstration projects.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

- Sec. 301. Medicare secondary payor (MSP) provisions.
- Sec. 302. Competitive acquisition of certain items and services.
- Sec. 303. Reform of payment for drugs and biologicals under the medicare program.
- Sec. 304. Demonstration project for use of recovery audit contractors.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 401. Fairness in the medicare disproportionate share hospital (DSH) adjustment for rural hospitals.
- Sec. 402. Immediate establishment of uniform standardized amount in rural and small urban areas.
- Sec. 403. Establishment of essential rural hospital classification.
- Sec. 404. More frequent update in weights used in hospital market basket.
- Sec. 405. Improvements to critical access hospital program.
- Sec. 406. Redistribution of unused resident positions.
- Sec. 407. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under prospective payment system for hospital outpatient department services.
- Sec. 408. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
- Sec. 409. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
- Sec. 410. Improvement in payments to retain emergency capacity for ambulance services in rural areas.
- Sec. 411. Two-year increase for home health services furnished in a rural area.
- Sec. 412. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 413. GAO study of geographic differences in payments for physicians' services.



- Sec. 414. Treatment of missing cost reporting periods for sole community hospitals.
- Sec. 415. Extension of telemedicine demonstration project.
- Sec. 416. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.
- Sec. 417. Medicare incentive payment program improvements for physician scarcity.
- Sec. 418. Medicare inpatient hospital payment adjustment for low-volume hospitals.
- Sec. 419. Treatment of certain clinical diagnostic laboratory tests furnished by a sole community hospital.
- Sec. 420. Establishment of floor on geographic adjustments of payments for physicians' services.
- Sec. 421. Ambulance payment rates.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 501. Adjustment for indirect costs of medical education (IME).
- Sec. 502. Recognition of new medical technologies under inpatient hospital pps.
- Sec. 503. Increase in Federal rate for hospitals in Puerto Rico.
- Sec. 504. Wage index adjustment reclassification reform .
- Sec. 505. Clarifications to certain exceptions to medicare limits on physician referrals.

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
- Sec. 602. Studies on access to physicians' services.
- Sec. 603. MedPAC report on payment for physicians' services.

Subtitle B—Preventive Services

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cholesterol and blood lipid screening.
- Sec. 613. Waiver of deductible for colorectal cancer screening tests.
- Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Services

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Payment for ambulance services.
- Sec. 623. Renal dialysis services.
- Sec. 624. One-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Adjustment to payments for services furnished in ambulatory surgical centers.
- Sec. 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 628. Extension of coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
- Sec. 629. Medicare coverage of diabetes laboratory diagnostic tests.



TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. MedPAC study on medicare margins of home health agencies.
- Sec. 703. Demonstration project to clarify the definition of homebound.

Subtitle B—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Chronic care improvement under Medicare+Choice plans.
- Sec. 723. Institute of Medicine report.
- Sec. 724. MedPAC report.

Subtitle C—Other Provisions

- Sec. 731. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 732. Demonstration project for medical adult day care services.
- Sec. 733. Improvements in national and local coverage determination process to respond to changes in technology.
- Sec. 734. Treatment of certain physician pathology services.
- Sec. 735. Medicare pancreatic islet cell transplant demonstration project.

TITLE VIII—MEDICAID

- Sec. 801. Continuation of medicaid DSH allotment adjustments under BIPA 2000.
- Sec. 802. Increase in floor for treatment as an extremely low DSH State to 3 percent in fiscal year 2003.
- Sec. 803. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

- Sec. 901. Construction; definition of supplier.
- Sec. 902. Issuance of regulations.
- Sec. 903. Compliance with changes in regulations and policies.
- Sec. 904. Reports and studies relating to regulatory reform.

Subtitle B—Contracting Reform

- Sec. 911. Increased flexibility in medicare administration.
- Sec. 912. Requirements for information security for medicare administrative contractors.

Subtitle C—Education and Outreach

- Sec. 921. Provider education and technical assistance.
- Sec. 922. Small provider technical assistance demonstration program.
- Sec. 923. Medicare provider ombudsman; medicare beneficiary ombudsman.
- Sec. 924. Beneficiary outreach demonstration program.
- Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
- Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Subtitle D—Appeals and Recovery

- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.



- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
- Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.

Subtitle V—Miscellaneous Provisions

- Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 942. Improvement in oversight of technology and coverage.
- Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
- Sec. 944. EMTALA improvements.
- Sec. 945. Emergency medical treatment and active labor act (EMTALA) technical advisory group.
- Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 947. Application of OSHA bloodborne pathogens standard to certain hospitals.
- Sec. 948. BIPA-related technical amendments and corrections.
- Sec. 949. Conforming authority to waive a program exclusion.
- Sec. 950. Treatment of certain dental claims.
- Sec. 951. Furnishing hospitals with information to compute dsh formula.
- Sec. 952. Revisions to reassignment provisions.
- Sec. 953. Other provisions.

TITLE X—IMPORTATION OF PRESCRIPTION DRUGS

- Sec. 1001. Importation of prescription drugs.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

- Sec. 1101. Short title.
- Sec. 1102. 30-month stay-of-effectiveness period.
- Sec. 1103. Forfeiture of 180-day exclusivity period.
- Sec. 1104. Bioavailability and bioequivalence.
- Sec. 1105. Remedies for infringement.
- Sec. 1106. Conforming amendments.



1 **TITLE I—MEDICARE PRESCRIP-**
2 **TION MEDICINE BENEFIT**

3 **SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRE-**
4 **SCRIPTION MEDICINE PROGRAM.**

5 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.)
6 is amended—

7 (1) by redesignating section 1859 and part D as sec-
8 tion 1858 and part E, respectively; and

9 (2) by inserting after part C the following new part:

10 “PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT
11 FOR THE AGED AND DISABLED

12 “MEDICARE OUTPATIENT PRESCRIPTION MEDICINE BENEFIT

13 “SEC. 1859. Subject to the succeeding provisions of this
14 part, the voluntary prescription medicine benefit program
15 under this part provides the following:

16 “(1) PREMIUM.—The monthly premium is \$25.

17 “(2) DEDUCTIBLE.—The annual deductible is \$100.

18 “(3) COINSURANCE.—The coinsurance is 20 percent.

19 “(4) OUT-OF-POCKET LIMIT.—The annual limit on
20 out-of-pocket spending on covered medicines is \$2,000.

21 “NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL
22 MANUFACTURERS

23 “SEC. 1859A. (a) AUTHORITY TO NEGOTIATE PRICES
24 WITH MANUFACTURERS.—The Secretary shall, consistent with
25 the requirements of this part and the goals of providing quality
26 care and containing costs under this part, negotiate contracts
27 with manufacturers of covered outpatient prescription medi-
28 cines that provide for the maximum prices that may be charged
29 to individuals enrolled under this part by participating phar-
30 macies for dispensing such medicines to such individuals.

31 “(b) PROMOTION OF BREAKTHROUGH MEDICINES.—In
32 conducting negotiations with manufacturers under this part,
33 the Secretary shall take into account the goal of promoting the
34 development of breakthrough medicines (as defined in section
35 1859H(b)).

36 “CONTRACT AUTHORITY

37 “SEC. 1859B. (a) CONTRACT AUTHORITY.—



1 “(1) IN GENERAL.—The Secretary is responsible for
2 the administration of this part and shall enter into con-
3 tracts with appropriate pharmacy contractors on a national
4 or regional basis to administer the benefits under this part.

5 “(2) PROCEDURES.—The Secretary shall establish
6 procedures under which the Secretary—

7 “(A) accepts bids submitted by entities to serve as
8 pharmacy contractors under this part in a region or on
9 a national basis;

10 “(B) awards contracts to such contractors to ad-
11 minister benefits under this part to eligible bene-
12 ficiaries in the region or on a national basis; and

13 “(C) provides for the termination (and non-
14 renewal) of a contract in the case of a contractor’s fail-
15 ure to meet the requirements of the contract and this
16 part.

17 “(3) COMPETITIVE PROCEDURES.—Competitive proce-
18 dures (as defined in section 4(5) of the Office of Federal
19 Procurement Policy Act (41 U.S.C. 403(5))) shall be used
20 to enter into contracts under this part.

21 “(4) TERMS AND CONDITIONS.—Such contracts shall
22 have such terms and conditions as the Secretary shall
23 specify and shall be for such terms (of at least 2 years, but
24 not to exceed 5 years) as the Secretary shall specify con-
25 sistent with this part.

26 “(5) USE OF PHARMACY CONTRACTORS IN PRICE NE-
27 GOTIATIONS.—Such contracts shall require the contractor
28 involved to negotiate contracts with manufacturers that
29 provide for maximum prices for covered outpatient pre-
30 scription medicines that are lower than the maximum
31 prices negotiated under section 1859A(a), if applicable. The
32 price reductions shall be passed on to eligible beneficiaries
33 and the Secretary shall hold the contractor accountable for
34 meeting performance requirements with respect to price re-
35 ductions and limiting price increases.

36 “(6) AREA FOR CONTRACTS.—

37 “(A) REGIONAL BASIS.—



1 “(i) IN GENERAL.—Except as provided in
2 clause (ii) and subject to subparagraph (B), the
3 contract entered into between the Secretary and a
4 pharmacy contractor shall require the contractor to
5 administer the benefits under this part in a region
6 determined by the Secretary under subparagraph
7 (B) or on a national basis.

8 “(ii) PARTIAL REGIONAL BASIS.—

9 “(I) IN GENERAL.—If determined appro-
10 priate by the Secretary, the Secretary may per-
11 mit the benefits to be administered in a partial
12 region determined appropriate by the Sec-
13 retary.

14 “(II) REQUIREMENTS.—If the Secretary
15 permits administration pursuant to subclause
16 (I), the Secretary shall ensure that the partial
17 region in which administration is effected is no
18 smaller than a State and is at least the size of
19 the commercial service area of the contractor
20 for that area.

21 “(B) DETERMINATION.—

22 “(i) IN GENERAL.—In determining regions for
23 contracts under this part, the Secretary shall—

24 “(I) take into account the number of indi-
25 viduals enrolled under this part in an area in
26 order to encourage participation by pharmacy
27 contractors; and

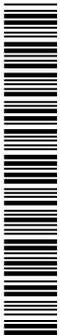
28 “(II) ensure that there are at least 10 dif-
29 ferent regions in the United States.

30 “(ii) NO ADMINISTRATIVE OR JUDICIAL RE-
31 VIEW.—The determination of administrative areas
32 under this paragraph shall not be subject to admin-
33 istrative or judicial review.

34 “(7) SUBMISSION OF BIDS.—

35 “(A) SUBMISSION.—

36 “(i) IN GENERAL.—Subject to subparagraph
37 (B), each entity desiring to serve as a pharmacy



1 contractor under this part in an area shall submit
2 a bid with respect to such area to the Secretary at
3 such time, in such manner, and accompanied by
4 such information as the Secretary may reasonably
5 require.

6 “(ii) BID THAT COVERS MULTIPLE AREAS.—
7 The Secretary shall permit an entity to submit a
8 single bid for multiple areas if the bid is applicable
9 to all such areas.

10 “(B) REQUIRED INFORMATION.—The bids de-
11 scribed in subparagraph (A) shall include—

12 “(i) a proposal for the estimated prices of cov-
13 ered outpatient prescription medicines and the pro-
14 jected annual increases in such prices, including
15 the additional reduction in price negotiated below
16 the Secretary’s maximum price and differentials be-
17 tween preferred and nonpreferred prices, if applica-
18 ble;

19 “(ii) a statement regarding the amount that
20 the entity will charge the Secretary for admin-
21 istering the benefits under the contract;

22 “(iii) a statement regarding whether the entity
23 will reduce the applicable coinsurance percentage
24 pursuant to section 1859E(a)(1)(A)(ii) and if so,
25 the amount of such reduction and how such reduc-
26 tion is tied to the performance requirements de-
27 scribed in subsection (c)(4)(A)(ii);

28 “(iv) a detailed description of the performance
29 requirements for which the administrative fee of
30 the entity will be subject to risk pursuant to sub-
31 section (c)(4)(A)(ii);

32 “(v) a detailed description of access to phar-
33 macy services provided by the entity, including in-
34 formation regarding whether the pharmacy con-
35 tractor will use a preferred pharmacy network, and,
36 if so, how the pharmacy contractor will ensure ac-
37 cess to pharmacies that choose to be outside of that



1 network, and whether there will be increased cost-
2 sharing for beneficiaries if they obtain medicines at
3 such pharmacies;

4 “(vi) a detailed description of the procedures
5 and standards the entity will use for—

6 “(I) selecting preferred prescription medi-
7 cines; and

8 “(II) determining when and how often the
9 list of preferred prescription medicines should
10 be modified;

11 “(vii) a detailed description of any ownership
12 or shared financial interests with pharmaceutical
13 manufacturers, pharmacies, and other entities in-
14 volved in the administration or delivery of benefits
15 under this part as proposed in the bid;

16 “(viii) a detailed description of the entity’s es-
17 timated marketing and advertising expenditures re-
18 lated to enrolling and retaining eligible bene-
19 ficiaries; and

20 “(ix) such other information that the Sec-
21 retary determines is necessary in order to carry out
22 this part, including information relating to the bid-
23 ding process under this part.

24 The procedures under clause (vi) shall include the use
25 of a pharmaceutical and therapeutics committee the
26 members of which include practicing pharmacists.

27 “(8) AWARDING OF CONTRACTS.—

28 “(A) NUMBER OF CONTRACTS.—The Secretary
29 shall, consistent with the requirements of this part and
30 the goals of providing quality care and of containing
31 costs under this part, award in a competitive manner
32 at least 2 contracts to administer benefits under this
33 part in each area specified under paragraph (6), unless
34 only 1 pharmacy contractor submitting a bid meets the
35 minimum standards specified under this part and by
36 the Secretary.



1 “(B) DETERMINATION.—In determining which of
2 the pharmacy contractors that submitted bids that
3 meet the minimum standards specified under this part
4 and by the Secretary to award a contract, the Sec-
5 retary shall consider the comparative merits of each
6 bid, as determined on the basis of relevant factors, with
7 respect to—

8 “(i) how well the contractor meets such min-
9 imum standards;

10 “(ii) the amount that the contractor will
11 charge the Secretary for administering the benefits
12 under the contract;

13 “(iii) the performance standards established
14 under subsection (c)(2) and performance require-
15 ments for which the administrative fee of the entity
16 will be subject to risk pursuant to subsection
17 (c)(4)(A)(ii);

18 “(iv) the proposed negotiated prices of covered
19 outpatient medicines and annual increases in such
20 prices;

21 “(v) factors relating to benefits, quality and
22 performance, beneficiary cost-sharing, and con-
23 sumer satisfaction;

24 “(vi) past performance and prior experience of
25 the contractor in administering a prescription med-
26 icine benefit program;

27 “(vii) effectiveness of the contractor in con-
28 taining costs through pricing incentives and utiliza-
29 tion management; and

30 “(viii) such other factors as the Secretary
31 deems necessary to evaluate the merits of each bid.

32 “(C) EXCEPTION TO CONFLICT OF INTEREST
33 RULES.—In awarding contracts with pharmacy contrac-
34 tors under this part, the Secretary may waive conflict
35 of interest laws generally applicable to Federal acquisi-
36 tions (subject to such safeguards as the Secretary may



1 find necessary to impose) in circumstances where the
2 Secretary finds that such waiver—

3 “(i) is not inconsistent with the—

4 “(I) purposes of the programs under this
5 part; or

6 “(II) best interests of beneficiaries en-
7 rolled under this part; and

8 “(ii) permits a sufficient level of competition
9 for such contracts, promotes efficiency of benefits
10 administration, or otherwise serves the objectives of
11 the program under this part.

12 “(D) NO ADMINISTRATIVE OR JUDICIAL RE-
13 VIEW.—The determination of the Secretary to award or
14 not award a contract to a pharmacy contractor under
15 this part shall not be subject to administrative or judi-
16 cial review.

17 “(9) ACCESS TO BENEFITS IN CERTAIN AREAS.—

18 “(A) AREAS NOT COVERED BY CONTRACTS.—The
19 Secretary shall develop procedures for the provision of
20 covered outpatient prescription medicines under this
21 part to each eligible beneficiary enrolled under this part
22 that resides in an area that is not covered by any con-
23 tract under this part.

24 “(B) BENEFICIARIES RESIDING IN DIFFERENT LO-
25 CATIONS.—The Secretary shall develop procedures to
26 ensure that each eligible beneficiary enrolled under this
27 part that resides in different areas in a year is provided
28 the benefits under this part throughout the entire year.

29 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS AND
30 PROGRAMS.—In consultation with appropriate pharmacy con-
31 tractors, pharmacists, and health care professionals with exper-
32 tise in prescribing, dispensing, and the appropriate use of pre-
33 scription medicines, the Secretary shall establish standards and
34 programs for the administration of this part to ensure appro-
35 priate prescribing, dispensing, and utilization of outpatient
36 medicines under this part, to avoid adverse medicine reactions,
37 and to continually reduce errors in the delivery of medically ap-



1 appropriate covered benefits. The Secretary shall not award a
2 contract to a pharmacy contractor under this part unless the
3 Secretary finds that the contractor agrees to comply with such
4 standards and programs and other terms and conditions as the
5 Secretary shall specify. The standards and programs under this
6 subsection shall be applied to any administrative agreements
7 described in subsection (a) the Secretary enters into. Such
8 standards and programs shall include the following:

9 “(1) ACCESS.—

10 “(A) IN GENERAL.—The pharmacy contractor
11 shall ensure that covered outpatient prescription medi-
12 cines are accessible and convenient to eligible bene-
13 ficiaries enrolled under this part for whom benefits are
14 administered by the pharmacy contractor, including by
15 offering the services 24 hours a day and 7 days a week
16 for emergencies.

17 “(B) ON-LINE REVIEW.—The pharmacy contractor
18 shall provide for on-line prospective review available 24
19 hours a day and 7 days a week in order to evaluate
20 each prescription for medicine therapy problems due to
21 duplication, interaction, or incorrect dosage or duration
22 of therapy.

23 “(C) GUARANTEED ACCESS TO MEDICINES IN
24 RURAL AND HARD-TO-SERVE AREAS.—The Secretary
25 shall ensure that all beneficiaries have guaranteed ac-
26 cess to the full range of pharmaceuticals under this
27 part, and shall give special attention to access, phar-
28 macist counseling, and delivery in rural and hard-to-
29 serve areas, including through the use of incentives
30 such as bonus payments to retail pharmacists in rural
31 areas and extra payments to the pharmacy contractor
32 for the cost of rapid delivery of pharmaceuticals and
33 any other actions necessary.

34 “(D) PREFERRED PHARMACY NETWORKS.—

35 “(i) IN GENERAL.—If a pharmacy contractor
36 uses a preferred pharmacy network to deliver bene-
37 fits under this part, such network shall meet min-



1 imum access standards established by the Sec-
2 retary.

3 “(ii) STANDARDS.—In establishing standards
4 under clause (i), the Secretary shall take into ac-
5 count reasonable distances to pharmacy services in
6 both urban and rural areas.

7 “(E) ADHERENCE TO NEGOTIATED PRICES.—The
8 pharmacy contractor shall have in place procedures to
9 assure compliance of pharmacies with the requirements
10 of subsection (d)(3)(C) (relating to adherence to nego-
11 tiated prices).

12 “(F) CONTINUITY OF CARE.—

13 “(i) IN GENERAL.—The pharmacy contractor
14 shall ensure that, in the case of an eligible bene-
15 ficiary who loses coverage under this part with such
16 entity under circumstances that would permit a
17 special election period (as established by the Sec-
18 retary under section 1859C(b)(3)), the contractor
19 will continue to provide coverage under this part to
20 such beneficiary until the beneficiary enrolls and
21 receives such coverage with another pharmacy con-
22 tractor under this part or, if eligible, with a
23 Medicare+Choice organization.

24 “(ii) LIMITED PERIOD.—In no event shall a
25 pharmacy contractor be required to provide the ex-
26 tended coverage required under clause (i) beyond
27 the date which is 30 days after the coverage with
28 such contractor would have terminated but for this
29 subparagraph.

30 “(2) ENROLLEE GUIDELINES.—The pharmacy con-
31 tractor shall, consistent with State law, apply guidelines for
32 counseling enrollees regarding—

33 “(A) the proper use of covered outpatient prescrip-
34 tion medicine; and

35 “(B) interactions and contra-indications.



1 “(3) EDUCATION.—The pharmacy contractor shall
2 apply methods to identify and educate providers, phar-
3 macists, and enrollees regarding—

4 “(A) instances or patterns concerning the unneces-
5 sary or inappropriate prescribing or dispensing of cov-
6 ered outpatient prescription medicines;

7 “(B) instances or patterns of substandard care;

8 “(C) potential adverse reactions to covered out-
9 patient prescription medicines;

10 “(D) inappropriate use of antibiotics;

11 “(E) appropriate use of generic products; and

12 “(F) the importance of using covered outpatient
13 prescription medicines in accordance with the instruc-
14 tion of prescribing providers.

15 “(4) COORDINATION.—The pharmacy contractor shall
16 coordinate with State prescription medicine programs,
17 other pharmacy contractors, pharmacies, and other relevant
18 entities as necessary to ensure appropriate coordination of
19 benefits with respect to enrolled individuals when such indi-
20 vidual is traveling outside the home service area, and under
21 such other circumstances as the Secretary may specify.

22 “(5) COST DATA.—

23 “(A) The pharmacy contractor shall make data on
24 prescription medicine negotiated prices (including data
25 on discounts) available to the Secretary.

26 “(B) The Secretary shall require, either directly or
27 through a pharmacy contractor, that participating
28 pharmacists, physicians, and manufacturers—

29 “(i) maintain their prescription medicine cost
30 data (including data on discounts) in a form and
31 manner specified by the Secretary;

32 “(ii) make such prescription medicine cost
33 data available for review and audit by the Sec-
34 retary; and

35 “(iii) certify that the prescription medicine
36 cost data are current, accurate, and complete, and
37 reflect all discounts obtained by the pharmacist or



1 physician in the purchasing of covered outpatient
2 prescription medicines.

3 Discounts referred to in subparagraphs (A) and (B) shall
4 include all volume discounts, manufacturer rebates, prompt
5 payment discounts, free goods, in-kind services, or any
6 other thing of financial value provided explicitly or implic-
7 itly in exchange for the purchase of a covered outpatient
8 prescription medicine.

9 “(6) REPORTING.—The pharmacy contractor shall
10 provide the Secretary with periodic reports on—

11 “(A) the contractor’s costs of administering this
12 part;

13 “(B) utilization of benefits under this part;

14 “(C) marketing and advertising expenditures re-
15 lated to enrolling and retaining individuals under this
16 part; and

17 “(D) grievances and appeals.

18 “(7) RECORDS AND AUDITS.—The pharmacy con-
19 tractor shall maintain adequate records related to the ad-
20 ministration of benefits under this part and afford the Sec-
21 retary access to such records for auditing purposes.

22 “(8) APPROVAL OF MARKETING MATERIAL AND APPLI-
23 CATION FORMS.—The pharmacy contractor shall comply
24 with requirements of section 1851(h) (relating to mar-
25 keting material and application forms) with respect to this
26 part in the same manner as such requirements apply under
27 part C, except that the provisions of paragraph (4)(A) of
28 such section shall not apply with respect to discounts or re-
29 bates provided in accordance with this part.

30 “(c) INCENTIVES FOR COST AND UTILIZATION MANAGE-
31 MENT AND QUALITY IMPROVEMENT.—

32 “(1) IN GENERAL.—The Secretary shall include in a
33 contract awarded under subsection (b) with a pharmacy
34 contractor such incentives for cost and utilization manage-
35 ment and quality improvement as the Secretary may deem
36 appropriate. The contract may provide financial or other



1 incentives to encourage greater savings to the program
2 under this part.

3 “(2) PERFORMANCE STANDARDS.—The Secretary shall
4 provide for performance standards (which may include
5 monetary bonuses if the standards are met and penalties
6 if the standards are not met), including standards relating
7 to the time taken to answer member and pharmacy inquir-
8 ies (written or by telephone), the accuracy of responses,
9 claims processing accuracy, online system availability, ap-
10 peal procedure turnaround time, system availability, the ac-
11 curacy and timeliness of reports, and level of beneficiary
12 satisfaction.

13 “(3) OTHER INCENTIVES.—Such incentives under this
14 subsection may also include—

15 “(A) financial incentives under which savings de-
16 rived from the substitution of generic and other pre-
17 ferred multi-source medicines in lieu of nongeneric and
18 nonpreferred medicines are made available to pharmacy
19 contractors, pharmacies, beneficiaries, and the Federal
20 Medicare Prescription Medicine Trust Fund; and

21 “(B) any other incentive that the Secretary deems
22 appropriate and likely to be effective in managing costs
23 or utilization or improving quality that does not reduce
24 the access of beneficiaries to medically necessary cov-
25 ered outpatient medicines.

26 “(4) REQUIREMENTS FOR PROCEDURES.—

27 “(A) IN GENERAL.—The Secretary shall establish
28 procedures for making payments to each pharmacy
29 contractor with a contract under this part for the ad-
30 ministration of the benefits under this part. The proce-
31 dures shall provide for the following:

32 “(i) ADMINISTRATIVE PAYMENT.—Payment of
33 administrative fees for such administration.

34 “(ii) RISK REQUIREMENT.—An adjustment of
35 a percentage (determined under subparagraph (B))
36 of the administrative fee payments made to a phar-
37 macy contractor to ensure that the contractor, in



1 administering the benefits under this part, pursues
2 performance requirements established by the Sec-
3 retary, including the following:

4 “(I) QUALITY SERVICE.—The contractor
5 provides eligible beneficiaries for whom it ad-
6 ministers benefits with quality services, as
7 measured by such factors as sustained phar-
8 macy network access, timeliness and accuracy
9 of service delivery in claims processing and
10 card production, pharmacy and member service
11 support access, and timely action with regard
12 to appeals and current beneficiary service sur-
13 veys.

14 “(II) QUALITY CLINICAL CARE.—The con-
15 tractor provides such beneficiaries with quality
16 clinical care, as measured by such factors as
17 providing notification to such beneficiaries and
18 to providers in order to prevent adverse drug
19 reactions and reduce medication errors and
20 specific clinical suggestions to improve health
21 and patient and prescriber education as appro-
22 priate.

23 “(III) CONTROL OF MEDICARE COSTS.—
24 The contractor contains costs under this part
25 to the Federal Medicare Prescription Medicine
26 Trust Fund and enrollees, as measured by ge-
27 neric substitution rates, price discounts, and
28 other factors determined appropriate by the
29 Secretary that do not reduce the access of
30 beneficiaries to medically necessary covered
31 outpatient prescription medicines.

32 “(B) PERCENTAGE OF PAYMENT TIED TO RISK.—

33 “(i) IN GENERAL.—Subject to clause (ii), the
34 Secretary shall determine the percentage of the ad-
35 ministrative payments to a pharmacy contractor
36 that will be tied to the performance requirements
37 described in subparagraph (A)(ii).



1 “(ii) LIMITATION ON RISK TO ENSURE PRO-
2 GRAM STABILITY.—In order to provide for program
3 stability, the Secretary may not establish a percent-
4 age to be adjusted under this paragraph at a level
5 that jeopardizes the ability of a pharmacy con-
6 tractor to administer the benefits under this part
7 or administer such benefits in a quality manner.

8 “(C) RISK ADJUSTMENT OF PAYMENTS BASED ON
9 ENROLLEES IN PLAN.—To the extent that a pharmacy
10 contractor is at risk under this paragraph, the proce-
11 dures established under this paragraph may include a
12 methodology for risk adjusting the payments made to
13 such contractor based on the differences in actuarial
14 risk of different enrollees being served if the Secretary
15 determines such adjustments to be necessary and ap-
16 propriate.

17 “(d) AUTHORITY RELATING TO PHARMACY PARTICIPA-
18 TION.—

19 “(1) IN GENERAL.—Subject to the succeeding provi-
20 sions of this subsection, a pharmacy contractor may estab-
21 lish consistent with this part conditions for the participa-
22 tion of pharmacies, including conditions relating to quality
23 (including reduction of medical errors) and technology.

24 “(2) AGREEMENTS WITH PHARMACIES.—Each phar-
25 macy contractor shall enter into a participation agreement
26 with any pharmacy that meets the requirements of this
27 subsection and section 1859E to furnish covered outpatient
28 prescription medicines to individuals enrolled under this
29 part.

30 “(3) TERMS OF AGREEMENT.—An agreement under
31 this subsection shall include the following terms and condi-
32 tions:

33 “(A) APPLICABLE REQUIREMENTS.—The phar-
34 macy shall meet (and throughout the contract period
35 continue to meet) all applicable Federal requirements
36 and State and local licensing requirements.



1 “(B) ACCESS AND QUALITY STANDARDS.—The
2 pharmacy shall comply with such standards as the Sec-
3 retary (and such a pharmacy contractor) shall establish
4 concerning the quality of, and enrolled individuals’ ac-
5 cess to, pharmacy services under this part. Such stand-
6 ards shall require the pharmacy—

7 “(i) not to refuse to dispense covered out-
8 patient prescription medicines to any individual en-
9 rolled under this part;

10 “(ii) to keep patient records (including records
11 on expenses) for all covered outpatient prescription
12 medicines dispensed to such enrolled individuals;

13 “(iii) to submit information (in a manner spec-
14 ified by the Secretary to be necessary to administer
15 this part) on all purchases of such medicines dis-
16 pensed to such enrolled individuals; and

17 “(iv) to comply with periodic audits to assure
18 compliance with the requirements of this part and
19 the accuracy of information submitted.

20 “(C) ADHERENCE TO NEGOTIATED PRICES.—(i)
21 The total charge for each medicine dispensed by the
22 pharmacy to an enrolled individual under this part,
23 without regard to whether the individual is financially
24 responsible for any or all of such charge, shall not ex-
25 ceed the price negotiated under section 1859A(a) or, if
26 lower, negotiated under subsection (a)(5) (or, if less,
27 the retail price for the medicine involved) with respect
28 to such medicine plus a reasonable dispensing fee de-
29 termined contractually with the pharmacy contractor.

30 “(ii) The pharmacy does not charge (or collect
31 from) an enrolled individual an amount that exceeds
32 the individual’s obligation (as determined in accordance
33 with the provisions of this part) of the applicable price
34 described in clause (i).

35 “(D) ADDITIONAL REQUIREMENTS.—The phar-
36 macy shall meet such additional contract requirements



1 as the applicable pharmacy contractor specifies under
2 this section.

3 “(4) APPLICABILITY OF FRAUD AND ABUSE PROVI-
4 SIONS.—The provisions of section 1128 through 1128C (re-
5 lating to fraud and abuse) apply to pharmacies partici-
6 pating in the program under this part.

7 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

8 “SEC. 1859C. (a) ELIGIBILITY.—Each individual who is
9 entitled to hospital insurance benefits under part A or is eligi-
10 ble to be enrolled in the medical insurance program under part
11 B is eligible to enroll in accordance with this section for out-
12 patient prescription medicine benefits under this part.

13 “(b) VOLUNTARY ENROLLMENT.—

14 “(1) IN GENERAL.—An individual may enroll under
15 this part only in such manner and form as may be pre-
16 scribed by regulations, and only during an enrollment pe-
17 riod prescribed in or under this subsection.

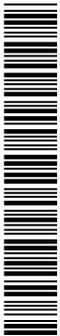
18 “(2) INITIAL ENROLLMENT PERIOD.—

19 “(A) INDIVIDUALS CURRENTLY COVERED.—In the
20 case of an individual who satisfies subsection (a) as of
21 November 1, 2005, the initial general enrollment period
22 shall begin on August 1, 2005, and shall end on March
23 1, 2006.

24 “(B) INDIVIDUAL COVERED IN FUTURE.—In the
25 case of an individual who first satisfies subsection (a)
26 on or after November 1, 2005, the individual’s initial
27 enrollment period shall begin on the first day of the
28 third month before the month in which such individual
29 first satisfies such paragraph and shall end seven
30 months later. The Secretary shall apply rules similar to
31 the rule described in the second sentence of section
32 1837(d).

33 “(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PRE-
34 MIUM PENALTY).—

35 “(A) EMPLOYER COVERAGE AT TIME OF INITIAL
36 GENERAL ENROLLMENT PERIOD.—In the case of an in-
37 dividual who—



1 “(i) at the time the individual first satisfies
2 subsection (a) is enrolled in a group health plan
3 (including continuation coverage) that provides out-
4 patient prescription medicine coverage by reason of
5 the individual’s (or the individual’s spouse’s) cur-
6 rent (or, in the case of continuation coverage,
7 former) employment status, and

8 “(ii) has elected not to enroll (or to be deemed
9 enrolled) under this subsection during the individ-
10 ual’s initial enrollment period,

11 there shall be a special enrollment period of 6 months
12 beginning with the first month that includes the date
13 of the individual’s (or individual’s spouse’s) retirement
14 from or termination of current employment status with
15 the employer that sponsors the plan, or, in the case of
16 continuation coverage, that includes the date of termi-
17 nation of such coverage, or that includes the date the
18 plan substantially terminates outpatient prescription
19 medicine coverage.

20 “(B) DROPPING OF RETIREE PRESCRIPTION MEDI-
21 CINE COVERAGE.—In the case of an individual who—

22 “(i) at the time the individual first satisfies
23 subsection (a) is enrolled in a group health plan
24 that provides outpatient prescription medicine cov-
25 erage other than by reason of the individual’s (or
26 the individual’s spouse’s) current employment; and

27 “(ii) has elected not to enroll (or to be deemed
28 enrolled) under this subsection during the individ-
29 ual’s initial enrollment period,

30 there shall be a special enrollment period of 6 months
31 beginning with the first month that includes the date
32 that the plan substantially terminates outpatient pre-
33 scription medicine coverage and ending 6 months later.

34 “(C) LOSS OF MEDICARE+CHOICE PRESCRIPTION
35 MEDICINE COVERAGE.—In the case of an individual
36 who is enrolled under part C in a Medicare+Choice
37 plan that provides prescription medicine benefits, if



1 such enrollment is terminated because of the termi-
2 nation or reduction in service area of the plan, there
3 shall be a special enrollment period of 6 months begin-
4 ning with the first month that includes the date that
5 such plan is terminated or such reduction occurs and
6 ending 6 months later.

7 “(D) LOSS OF MEDICAID PRESCRIPTION MEDICINE
8 COVERAGE.—In the case of an individual who—

9 “(i) satisfies subsection (a);

10 “(ii) loses eligibility for benefits (that include
11 benefits for prescription medicine) under a State
12 plan after having been enrolled (or determined to
13 be eligible) for such benefits under such plan; and

14 “(iii) is not otherwise enrolled under this sub-
15 section at the time of such loss of eligibility,

16 there shall be a special enrollment period specified by
17 the Secretary of not less than 6 months beginning with
18 the first month that includes the date that the indi-
19 vidual loses such eligibility.

20 “(4) LATE ENROLLMENT WITH PREMIUM PENALTY.—

21 The Secretary shall permit an individual who satisfies sub-
22 section (a) to enroll other than during the initial enrollment
23 period under paragraph (2) or a special enrollment period
24 under paragraph (3). But, in the case of such an enroll-
25 ment, the amount of the monthly premium of the individual
26 is subject to an increase under section 1859C(e)(1).

27 “(5) INFORMATION.—

28 “(A) IN GENERAL.—The Secretary shall broadly
29 distribute information to individuals who satisfy sub-
30 section (a) on the benefits provided under this part.
31 The Secretary shall periodically make available infor-
32 mation on the cost differentials to enrollees for the use
33 of generic medicines and other medicines.

34 “(B) TOLL-FREE HOTLINE.—The Secretary shall
35 maintain a toll-free telephone hotline (which may be a
36 hotline already used by the Secretary under this title)
37 for purposes of providing assistance to beneficiaries in



1 the program under this part, including responding to
2 questions concerning coverage, enrollment, benefits,
3 grievances and appeals procedures, and other aspects of
4 such program.

5 “(6) ENROLLEE DEFINED.—For purposes of this part,
6 the term ‘enrollee’ means an individual enrolled for benefits
7 under this part.

8 “(c) COVERAGE PERIOD.—

9 “(1) IN GENERAL.—The period during which an indi-
10 vidual is entitled to benefits under this part (in this sub-
11 section referred to as the individual’s ‘coverage period’)
12 shall begin on such a date as the Secretary shall establish
13 consistent with the type of coverage rules described in sub-
14 sections (a) and (e) of section 1838, except that in no case
15 shall a coverage period begin before January 1, 2006. No
16 payments may be made under this part with respect to the
17 expenses of an individual unless such expenses were in-
18 curred by such individual during a period which, with re-
19 spect to the individual, is a coverage period.

20 “(2) TERMINATION.—The Secretary shall provide for
21 the application of provisions under this subsection similar
22 to the provisions in section 1838(b).

23 “(d) PROVISION OF BENEFITS TO MEDICARE+CHOICE
24 ENROLLEES.—In the case of an individual who is enrolled
25 under this part and is enrolled in a Medicare+Choice plan
26 under part C, the individual shall be provided the benefits
27 under this part through such plan and not through payment
28 under this part.

29 “(e) LATE ENROLLMENT PENALTIES; PAYMENT OF PRE-
30 MIUMS.—

31 “(1) LATE ENROLLMENT PENALTY.—

32 “(A) IN GENERAL.—In the case of a late enroll-
33 ment described in subsection (b)(4), subject to the suc-
34 ceeding provisions of this paragraph, the Secretary
35 shall establish procedures for increasing the amount of
36 the monthly premium under this part applicable to



1 such enrollee by an amount that the Secretary deter-
2 mines is actuarially sound for each such period.

3 “(B) PERIODS TAKEN INTO ACCOUNT.—For pur-
4 poses of calculating any 12-month period under sub-
5 paragraph (A), there shall be taken into account
6 months of lapsed coverage in a manner comparable to
7 that applicable under the second sentence of section
8 1839(b).

9 “(C) PERIODS NOT TAKEN INTO ACCOUNT.—

10 “(i) IN GENERAL.—For purposes of calcu-
11 lating any 12-month period under subparagraph
12 (A), subject to clause (ii), there shall not be taken
13 into account months for which the enrollee can
14 demonstrate that the enrollee was covered under a
15 group health plan that provides coverage of the
16 cost of prescription medicines whose actuarial value
17 (as defined by the Secretary) to the enrollee equals
18 or exceeds the actuarial value of the benefits pro-
19 vided to an individual enrolled in the outpatient
20 prescription medicine benefit program under this
21 part.

22 “(ii) APPLICATION.—This subparagraph shall
23 only apply with respect to a coverage period the en-
24 rollment for which occurs before the end of the 60-
25 day period that begins on the first day of the
26 month which includes the date on which the plan
27 terminates or reduces its service area (in a manner
28 that results in termination of enrollment), ceases to
29 provide, or reduces the value of the prescription
30 medicine coverage under such plan to below the
31 value of the coverage provided under the program
32 under this part.

33 “(2) INCORPORATION OF PREMIUM PAYMENT AND
34 GOVERNMENT CONTRIBUTIONS PROVISIONS.—The provi-
35 sions of sections 1840 and 1844(a)(1) shall apply to enroll-
36 ees under this part in the same manner as they apply to
37 individuals 65 years of age or older enrolled under part B.



1 For purposes of this subsection, any reference in a section
2 referred to in a previous subsection to the Federal Supple-
3 mentary Medical Insurance Trust Fund is deemed a ref-
4 erence to the Federal Medicare Prescription Medicine Trust
5 Fund.

6 “(f) ELECTION OF PHARMACY CONTRACTOR TO ADMIN-
7 ISTER BENEFITS.—The Secretary shall establish a process
8 whereby each individual enrolled under this part and residing
9 in a region may elect the pharmacy contractor that will admin-
10 ister the benefits under this part with respect to the individual.
11 Such process shall permit the individual to make an initial elec-
12 tion and to change such an election on at least an annual basis
13 and under such other circumstances as the Secretary shall
14 specify.

15 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS

16 “SEC. 1859D. (a) BENEFITS.—Subject to the succeeding
17 provisions of this section, the benefits provided to an enrollee
18 by the program under this part shall consist of the following:

19 “(1) COVERED OUTPATIENT PRESCRIPTION MEDICINE
20 BENEFITS.—Entitlement to have payment made on the in-
21 dividual’s behalf for covered outpatient prescription medi-
22 cines.

23 “(2) LIMITATION ON COST-SHARING FOR PART B OUT-
24 PATIENT PRESCRIPTION MEDICINES.—

25 “(A) IN GENERAL.—Once an enrollee has incurred
26 aggregate countable cost-sharing (as defined in sub-
27 paragraph (B)) equal to the stop-loss limit specified in
28 subsection (c)(4) for expenses in a year, entitlement to
29 the elimination of cost-sharing otherwise applicable
30 under part B for additional expenses incurred in the
31 year for outpatient prescription medicines or biologicals
32 for which payment is made under part B.

33 “(B) COUNTABLE COST-SHARING DEFINED.—For
34 purposes of this part, the term ‘countable cost-sharing’
35 means—



1 “(i) out-of-pocket expenses for outpatient pre-
2 scription medicines with respect to which benefits
3 are payable under part B, and

4 “(ii) cost-sharing under subsections (c)(3)(B)
5 and (c)(3)(C)(i).

6 “(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE
7 DEFINED.—

8 “(1) IN GENERAL.—Except as provided in paragraph
9 (2), for purposes of this part the term ‘covered outpatient
10 prescription medicine’ means any of the following products:

11 “(A) A medicine which may be dispensed only
12 upon prescription, and—

13 “(i) which is approved for safety and effective-
14 ness as a prescription medicine under section 505
15 of the Federal Food, Drug, and Cosmetic Act;

16 “(ii)(I) which was commercially used or sold in
17 the United States before the date of enactment of
18 the Drug Amendments of 1962 or which is iden-
19 tical, similar, or related (within the meaning of sec-
20 tion 310.6(b)(1) of title 21 of the Code of Federal
21 Regulations) to such a medicine, and (II) which
22 has not been the subject of a final determination
23 by the Secretary that it is a ‘new drug’ (within the
24 meaning of section 201(p) of the Federal Food,
25 Drug, and Cosmetic Act) or an action brought by
26 the Secretary under section 301, 302(a), or 304(a)
27 of such Act to enforce section 502(f) or 505(a) of
28 such Act; or

29 “(iii)(I) which is described in section 107(c)(3)
30 of the Drug Amendments of 1962 and for which
31 the Secretary has determined there is a compelling
32 justification for its medical need, or is identical,
33 similar, or related (within the meaning of section
34 310.6(b)(1) of title 21 of the Code of Federal Reg-
35 ulations) to such a medicine, and (II) for which the
36 Secretary has not issued a notice of an opportunity
37 for a hearing under section 505(e) of the Federal



1 Food, Drug, and Cosmetic Act on a proposed order
2 of the Secretary to withdraw approval of an appli-
3 cation for such medicine under such section be-
4 cause the Secretary has determined that the medi-
5 cine is less than effective for all conditions of use
6 prescribed, recommended, or suggested in its label-
7 ing.

8 “(B) A biological product which—

9 “(i) may only be dispensed upon prescription;

10 “(ii) is licensed under section 351 of the Pub-
11 lic Health Service Act; and

12 “(iii) is produced at an establishment licensed
13 under such section to produce such product.

14 “(C) Insulin approved under appropriate Federal
15 law, and needles, syringes, and disposable pumps for
16 the administration of such insulin.

17 “(D) A prescribed medicine or biological product
18 that would meet the requirements of subparagraph (A)
19 or (B) but that is available over-the-counter in addition
20 to being available upon prescription, but only if the
21 particular dosage form or strength prescribed and re-
22 quired for the individual is not available over-the-
23 counter.

24 “(E) Smoking cessation agents (as specified by the
25 Secretary).

26 “(2) EXCLUSION.—The term ‘covered outpatient pre-
27 scription medicine’ does not include—

28 “(A) medicines or classes of medicines, or their
29 medical uses, which may be excluded from coverage or
30 otherwise restricted under section 1927(d)(2), other
31 than subparagraph (E) thereof (relating to smoking
32 cessation agents), as the Secretary may specify and
33 does not include such other medicines, classes, and uses
34 as the Secretary may specify consistent with the goals
35 of providing quality care and containing costs under
36 this part;



1 “(B) except as provided in paragraphs (1)(D) and
2 (1)(E), any product which may be distributed to indi-
3 viduals without a prescription;

4 “(C) any product when furnished as part of, or as
5 incident to, a diagnostic service or any other item or
6 service for which payment may be made under this
7 title; or

8 “(D) any product that is covered under part B of
9 this title.

10 “(c) PAYMENT OF BENEFITS.—

11 “(1) COVERED OUTPATIENT PRESCRIPTION MEDI-
12 CINES.—There shall be paid from the Federal Medicare
13 Prescription Medicine Trust Fund, in the case of each en-
14 rollee who incurs expenses for medicines with respect to
15 which benefits are payable under this part under subsection
16 (a)(1), amounts equal to the sum of—

17 “(A) the price for which the medicine is made
18 available under this part (consistent with sections
19 1859A and 1859B), reduced by any applicable cost-
20 sharing under paragraphs (2) and (3); and

21 “(B) a reasonable dispensing fee.

22 The price under subparagraph (A) shall in no case exceed
23 the retail price for the medicine involved.

24 “(2) DEDUCTIBLE.—The amount of payment under
25 paragraph (1) for expenses incurred in a year, beginning
26 with 2006, shall be reduced by an annual deductible equal
27 to the amount specified in section 1859(2) (subject to ad-
28 justment under paragraph (8)). Only expenses for count-
29 able cost-sharing (as defined in subsection (a)(2)(B)) shall
30 be taken into account in applying this paragraph.

31 “(3) COINSURANCE.—

32 “(A) IN GENERAL.—The amount of payment
33 under paragraph (1) for expenses incurred in a year
34 shall be further reduced (subject to the stop-loss limit
35 under paragraph (4)) by coinsurance as provided under
36 this paragraph.



1 “(B) PREFERRED MEDICINES.—The coinsurance
2 under this paragraph in the case of a preferred medi-
3 cine (including a medicine treated as a preferred medi-
4 cine under paragraph (5)), is equal to 20 percent of the
5 price applicable under paragraph (1)(A) (or such lower
6 percentage as may be provided for under section
7 1859E(a)(1)(A)(ii)). In this part, the term ‘preferred
8 medicine’ means, with respect to medicines classified
9 within a therapeutic class, those medicines which have
10 been designated as a preferred medicine by the Sec-
11 retary or the pharmacy contractor involved with respect
12 to that class and (in the case of a nongeneric medicine)
13 with respect to which a contract has been negotiated
14 under this part.

15 “(C) NONPREFERRED MEDICINES.—The coinsur-
16 ance under this paragraph in the case of a nonpre-
17 ferred medicine that is not treated as a preferred medi-
18 cine under paragraph (5) is equal to the sum of—

19 “(i) 20 percent of the price for lowest price
20 preferred medicine that is within the same thera-
21 peutic class; and

22 “(ii) the amount by which—

23 “(I) the price at which the nonpreferred
24 medicine is made available to the enrollee; ex-
25 ceeds

26 “(II) the price of such lowest price pre-
27 ferred medicine.

28 “(4) NO COINSURANCE ONCE OUT-OF-POCKET EX-
29 PENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee
30 has incurred aggregate countable cost-sharing under para-
31 graph (3) (including cost-sharing under part B attributable
32 to outpatient prescription drugs or biologicals) equal to the
33 amount specified in section 1859(4) (subject to adjustment
34 under paragraph (8)) for expenses in a year—

35 “(A) there shall be no coinsurance under para-
36 graph (3) for additional expenses incurred in the year
37 involved; and



1 “(B) there shall be no coinsurance under part B
2 for additional expenses incurred in the year involved for
3 outpatient prescription drugs and biologicals.

4 “(5) APPEALS RIGHTS RELATING TO COVERAGE OF
5 NONPREFERRED MEDICINES.—

6 “(A) PROCEDURES REGARDING THE DETERMINA-
7 TION OF MEDICINES THAT ARE MEDICALLY NEC-
8 CESSARY.—Each pharmacy contractor shall have in
9 place procedures on a case-by-case basis to treat a non-
10 preferred medicine as a preferred medicine under this
11 part if the preferred medicine is determined to be not
12 as effective for the enrollee or to have significant ad-
13 verse effect on the enrollee. Such procedures shall re-
14 quire that such determinations are based on profes-
15 sional medical judgment, the medical condition of the
16 enrollee, and other medical evidence.

17 “(B) PROCEDURES REGARDING DENIALS OF
18 CARE.—Such contractor shall have in place procedures
19 to ensure—

20 “(i) a timely internal review for resolution of
21 denials of coverage (in whole or in part and includ-
22 ing those regarding the coverage of nonpreferred
23 medicines) in accordance with the medical exigen-
24 cies of the case and a timely resolution of com-
25 plaints, by enrollees in the plan, or by providers,
26 pharmacists, and other individuals acting on behalf
27 of each such enrollee (with the enrollee’s consent)
28 in accordance with requirements (as established by
29 the Secretary) that are comparable to such require-
30 ments for Medicare+Choice organizations under
31 part C;

32 “(ii) that the entity complies in a timely man-
33 ner with requirements established by the Secretary
34 that (I) provide for an external review by an inde-
35 pendent entity selected by the Secretary of denials
36 of coverage described in clause (i) not resolved in
37 the favor of the beneficiary (or other complainant)



1 under the process described in such clause and (II)
2 are comparable to the external review requirements
3 established for Medicare+Choice organizations
4 under part C; and

5 “(iii) that enrollees are provided with informa-
6 tion regarding the appeals procedures under this
7 part at the time of enrollment with a pharmacy
8 contractor under this part and upon request there-
9 after.

10 “(6) TRANSFER OF FUNDS TO COVER COSTS OF PART
11 B PRESCRIPTION MEDICINE CATASTROPHIC BENEFIT.—
12 With respect to benefits described in subsection (a)(2),
13 there shall transferred from the Federal Medicare Prescrip-
14 tion Medicine Trust Fund to the Federal Supplementary
15 Medical Insurance Trust Fund amounts equivalent to the
16 elimination of cost-sharing described in such subsection.

17 “(7) PERMITTING APPLICATION UNDER PART B OF
18 NEGOTIATED PRICES.—For purposes of making payment
19 under part B for medicines that would be covered out-
20 patient prescription medicines but for the exclusion under
21 subparagraph (B) or (C) of subsection (b)(2), the Secretary
22 may elect to apply the payment basis used for payment of
23 covered outpatient prescription medicines under this part
24 instead of the payment basis otherwise used under such
25 part, if it results in a lower cost to the program.

26 “(8) INFLATION ADJUSTMENT.—

27 “(A) IN GENERAL.—With respect to expenses in-
28 curred in a year after 2006—

29 “(i) the deductible under paragraph (2) is
30 equal to the deductible determined under such
31 paragraph (or this subparagraph) for the previous
32 year increased by the percentage increase in per
33 capita program expenditures (as estimated in ad-
34 vance for the year involved under subparagraph
35 (B)); and

36 “(ii) the stop-loss limit under paragraph (3) is
37 equal to the stop-loss limit determined under such



1 paragraph (or this subparagraph) for the previous
2 year increased by such percentage increase.

3 The Secretary shall adjust such percentage increase in
4 subsequent years to take into account misestimations
5 made of the per capita program expenditures under
6 clauses (i) and (ii) in previous years. Any increase
7 under this subparagraph that is not a multiple of \$10
8 shall be rounded to the nearest multiple of \$10.

9 “(B) ESTIMATION OF INCREASE IN PER CAPITA
10 PROGRAM EXPENDITURES.—The Secretary shall before
11 the beginning of each year (beginning with 2007) esti-
12 mate the percentage increase in average per capita ag-
13 gregate expenditures from the Federal Medicare Pre-
14 scription Medicine Trust Fund for the year involved
15 compared to the previous year.

16 “(C) RECONCILIATION.—The Secretary shall also
17 compute (beginning with 2008) the actual percentage
18 increase in such aggregate expenditures in order to
19 provide for reconciliation of deductibles, stop-loss lim-
20 its, and premiums under the second sentence of sub-
21 paragraph (A) and under section 1859D(d)(2).

22 “(d) AMOUNT OF PREMIUMS.—

23 “(1) MONTHLY PREMIUM RATE IN 2006.—The monthly
24 premium rate in 2006 for prescription medicine benefits
25 under this part is the amount specified in section 1859(1).

26 “(2) INFLATION ADJUSTMENT FOR SUBSEQUENT
27 YEARS.—The monthly premium rate for a year after 2006
28 for prescription medicine benefits under this part is equal
29 to the monthly premium rate for the previous year under
30 this subsection increased by the percentage increase in per
31 capita program expenditures (as estimated in advance for
32 the year involved under subsection (c)(8)(B)). The Sec-
33 retary shall adjust such percentage in subsequent years to
34 take into account misestimations made of the per capita
35 program expenditures under the previous sentence in pre-
36 vious years. Any increase under this paragraph that is not



1 a multiple of \$1 shall be rounded to the nearest multiple
2 of \$1.

3 “ADMINISTRATION; QUALITY ASSURANCE

4 “SEC. 1859E. (a) RULES RELATING TO PROVISION OF
5 BENEFITS.—

6 “(1) PROVISION OF BENEFITS.—

7 “(A) IN GENERAL.—In providing benefits under
8 this part, the Secretary (directly or through the con-
9 tracts with pharmacy contractors) shall employ mecha-
10 nisms to provide benefits appropriately and efficiently,
11 and those mechanisms may include—

12 “(i) the use of—

13 “(I) price negotiations (consistent with
14 subsection (b));

15 “(II) reduced coinsurance (below 20 per-
16 cent) to encourage the utilization of appro-
17 priate preferred medicines; and

18 “(III) methods to reduce medication errors
19 and encourage appropriate use of medications;
20 and

21 “(ii) permitting pharmacy contractors, as ap-
22 proved by the Secretary, to make exceptions to sec-
23 tion 1859D(c)(3)(C) (relating to cost-sharing for
24 non-preferred medicines) to secure best prices for
25 enrollees so long as the payment amount under sec-
26 tion 1859D(c)(1) does not equal zero.

27 “(B) CONSTRUCTION.—Nothing in this subsection
28 shall be construed to prevent the Secretary (directly or
29 through the contracts with pharmacy contractors) from
30 using incentives to encourage enrollees to select generic
31 or other cost-effective medicines, so long as—

32 “(i) such incentives are designed not to result
33 in any increase in the aggregate expenditures under
34 the Federal Medicare Prescription Medicine Trust
35 Fund; and

36 “(ii) a beneficiary’s coinsurance shall be no
37 greater than 20 percent in the case of a preferred



1 medicine (including a nonpreferred medicine treat-
2 ed as a preferred medicine under section
3 1859D(c)(5)).

4 “(2) CONSTRUCTION.—Nothing in this part shall pre-
5 clude the Secretary or a pharmacy contractor from—

6 “(A) educating prescribing providers, pharmacists,
7 and enrollees about medical and cost benefits of pre-
8 ferred medicines;

9 “(B) requesting prescribing providers to consider a
10 preferred medicine prior to dispensing of a nonpre-
11 ferred medicine, as long as such request does not un-
12 duly delay the provision of the medicine;

13 “(C) using mechanisms to encourage enrollees
14 under this part to select cost-effective medicines or less
15 costly means of receiving or administering medicines,
16 including the use of therapeutic interchange programs,
17 disease management programs, and notification to the
18 beneficiary that a more affordable generic medicine
19 equivalent was not selected by the prescribing provider
20 and a statement of the lost cost savings to the bene-
21 ficiary;

22 “(D) using price negotiations to achieve reduced
23 prices on covered outpatient prescription medicines, in-
24 cluding new medicines, medicines for which there are
25 few therapeutic alternatives, and medicines of par-
26 ticular clinical importance to individuals enrolled under
27 this part; and

28 “(E) utilizing information on medicine prices of
29 OECD countries and of other payors in the United
30 States in the negotiation of prices under this part.

31 “(b) PRICE NEGOTIATIONS PROCESS.—

32 “(1) REQUIREMENTS WITH RESPECT TO PREFERRED
33 MEDICINES.—Negotiations of contracts with manufacturers
34 with respect to covered outpatient prescription medicines
35 under this part shall be conducted in a manner so that—

36 “(A) there is at least a contract for a medicine
37 within each therapeutic class (as defined by the Sec-



1 retary in consultation with such Medicare Prescription
2 Medicine Advisory Committee);

3 “(B) if there is more than 1 medicine available in
4 a therapeutic class, there are contracts for at least 2
5 medicines within such class unless determined clinically
6 inappropriate in accordance with standards established
7 by the Secretary; and

8 “(C) if there are more than 2 medicines available
9 in a therapeutic class, there is a contract for at least
10 2 medicines within such class and a contract for ge-
11 neric medicine substitute if available unless determined
12 clinically inappropriate in accordance with standards
13 established by the Secretary.

14 “(2) ESTABLISHMENT OF THERAPEUTIC CLASSES.—
15 The Secretary, in consultation with the Medicare Prescrip-
16 tion Medicine Advisory Committee (established under sec-
17 tion 1859H), shall establish for purposes of this part thera-
18 peutic classes and assign to such classes covered outpatient
19 prescription medicines.

20 “(3) DISCLOSURE CONCERNING PREFERRED MEDI-
21 CINES.—The Secretary shall provide, through pharmacy
22 contractors or otherwise, for—

23 “(A) disclosure to current and prospective enroll-
24 ees and to participating providers and pharmacies in
25 each service area a list of the preferred medicines and
26 differences in applicable cost-sharing between such
27 medicines and nonpreferred medicines; and

28 “(B) advance disclosure to current enrollees and
29 to participating providers and pharmacies in each serv-
30 ice area of changes to any such list of preferred medi-
31 cines and differences in applicable cost-sharing.

32 “(4) NO REVIEW.—The Secretary’s establishment of
33 therapeutic classes and the assignment of medicines to such
34 classes and the Secretary’s determination of what is a
35 breakthrough medicine are not subject to administrative or
36 judicial review.



1 “(c) CONFIDENTIALITY.—The Secretary shall ensure that
2 the confidentiality of individually identifiable health information
3 relating to the provision of benefits under this part is pro-
4 tected, consistent with the standards for the privacy of such in-
5 formation promulgated by the Secretary under the Health In-
6 surance Portability and Accountability Act of 1996, or any sub-
7 sequent comprehensive and more protective set of confiden-
8 tiality standards enacted into law or promulgated by the Sec-
9 retary. Nothing in this subsection shall be construed as pre-
10 venting the coordination of data with a State prescription medi-
11 cine program so long as such program has in place confiden-
12 tiality standards that are equal to or exceed the standards used
13 by the Secretary.

14 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary,
15 through the Office of the Inspector General, is authorized and
16 directed to issue regulations establishing appropriate safe-
17 guards to prevent fraud and abuse under this part. Such safe-
18 guards, at a minimum, should include compliance programs,
19 certification data, audits, and recordkeeping practices. In devel-
20 oping such regulations, the Secretary shall consult with the At-
21 torney General and other law enforcement and regulatory agen-
22 cies.

23 “FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST FUND

24 “SEC. 1859F. (a) ESTABLISHMENT.—There is hereby cre-
25 ated on the books of the Treasury of the United States a trust
26 fund to be known as the ‘Federal Medicare Prescription Medi-
27 cine Trust Fund’ (in this section referred to as the ‘Trust
28 Fund’). The Trust Fund shall consist of such gifts and be-
29 quests as may be made as provided in section 201(i)(1), and
30 such amounts as may be deposited in, or appropriated to, such
31 fund as provided in this part.

32 “(b) APPLICATION OF SMI TRUST FUND PROVISIONS.—
33 The provisions of subsections (b) through (i) of section 1841
34 shall apply to this part and the Trust Fund in the same man-
35 ner as they apply to part B and the Federal Supplementary
36 Medical Insurance Trust Fund, respectively.



1 under the plan falls below the actuarial value re-
2 quired under subsection (a).

3 “(3) BENEFICIARY INFORMATION.—The sponsor of
4 the plan shall report to the Secretary, for each calendar
5 quarter for which it seeks a payment under this section, the
6 names and social security numbers of all enrollees described
7 in subsection (a) covered under such plan during such
8 quarter and the dates (if less than the full quarter) during
9 which each such individual was covered.

10 “(4) AUDITS.—The sponsor or plan seeking payment
11 under this section shall agree to maintain, and to afford
12 the Secretary access to, such records as the Secretary may
13 require for purposes of audits and other oversight activities
14 necessary to ensure the adequacy of prescription medicine
15 coverage, the accuracy of payments made, and such other
16 matters as may be appropriate.

17 “(c) PAYMENT.—

18 “(1) IN GENERAL.—The sponsor of a group health
19 plan that meets the requirements of subsection (b) with re-
20 spect to a quarter in a calendar year shall be entitled to
21 have payment made on a quarterly basis of the amount
22 specified in paragraph (2) for each individual described in
23 subsection (a) who during the quarter is covered under the
24 plan and was not enrolled in the insurance program under
25 this part.

26 “(2) AMOUNT OF PAYMENT.—

27 “(A) IN GENERAL.—The amount of the payment
28 for a quarter shall approximate, for each such covered
29 individual, $\frac{2}{3}$ of the sum of the monthly Government
30 contribution amounts (computed under subparagraph
31 (B)) for each of the 3 months in the quarter.

32 “(B) COMPUTATION OF MONTHLY GOVERNMENT
33 CONTRIBUTION AMOUNT.—For purposes of subpara-
34 graph (A), the monthly Government contribution
35 amount for a month in a year is equal to the amount
36 by which—



1 “(i) $\frac{1}{12}$ of the average per capita aggregate
2 expenditures, as estimated under section
3 1859D(c)(8) for the year involved; exceeds

4 “(ii) the monthly premium rate under section
5 1859D(d) for the month involved.

6 “MEDICARE PRESCRIPTION MEDICINE ADVISORY COMMITTEE

7 “SEC. 1859H. (a) ESTABLISHMENT OF COMMITTEE.—
8 There is established a Medicare Prescription Medicine Advisory
9 Committee (in this section referred to as the ‘Committee’).

10 “(b) FUNCTIONS OF COMMITTEE.—The Committee shall
11 advise the Secretary on policies related to—

12 “(1) the development of guidelines for the implementa-
13 tion and administration of the outpatient prescription medi-
14 cine benefit program under this part; and

15 “(2) the development of—

16 “(A) standards required of pharmacy contractors
17 under section 1859D(c)(5) for determining if a medi-
18 cine is as effective for an enrollee or has a significant
19 adverse effect on an enrollee under this part;

20 “(B) standards for—

21 “(i) defining therapeutic classes;

22 “(ii) adding new therapeutic classes;

23 “(iii) assigning to such classes covered out-
24 patient prescription medicines; and

25 “(iv) identifying breakthrough medicines;

26 “(C) procedures to evaluate the bids submitted by
27 pharmacy contractors under this part;

28 “(D) procedures for negotiations, and standards
29 for entering into contracts, with manufacturers, includ-
30 ing identifying medicines or classes of medicines where
31 Secretarial negotiation is most likely to yield savings
32 under this part significantly above those that which
33 could be achieved by a pharmacy contractor; and

34 “(E) procedures to ensure that pharmacy contrac-
35 tors with a contract under this part are in compliance
36 with the requirements under this part.



1 For purposes of this part, a medicine is a ‘breakthrough medi-
2 cine’ if the Secretary, in consultation with the Committee, de-
3 termines it is a new product that will make a significant and
4 major improvement by reducing physical or mental illness, re-
5 ducing mortality, or reducing disability, and that no other
6 product is available to beneficiaries that achieves similar results
7 for the same condition. The Committee may consider cost-effec-
8 tiveness in establishing standards for defining therapeutic
9 classes and assigning drugs to such classes under subparagraph
10 (B).

11 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
12 MITTEE.—

13 “(1) STRUCTURE.—The Committee shall be composed
14 of 19 members who shall be appointed by the Secretary.

15 “(2) MEMBERSHIP.—

16 “(A) IN GENERAL.—The members of the Com-
17 mittee shall be chosen on the basis of their integrity,
18 impartiality, and good judgment, and shall be individ-
19 uals who are, by reason of their education, experience,
20 and attainments, exceptionally qualified to perform the
21 duties of members of the Committee.

22 “(B) SPECIFIC MEMBERS.—Of the members ap-
23 pointed under paragraph (1)—

24 “(i) 5 shall be chosen to represent practicing
25 physicians, 2 of whom shall be gerontologists;

26 “(ii) 2 shall be chosen to represent practicing
27 nurse practitioners;

28 “(iii) 4 shall be chosen to represent practicing
29 pharmacists;

30 “(iv) 1 shall be chosen to represent the Cen-
31 ters for Medicare & Medicaid Services;

32 “(v) 4 shall be chosen to represent actuaries,
33 pharmacoeconomists, researchers, and other appro-
34 priate experts;

35 “(vi) 1 shall be chosen to represent emerging
36 medicine technologies;



1 “(vii) 1 shall be chosen to represent the Food
2 and Drug Administration; and

3 “(viii) 1 shall be chosen to represent individ-
4 uals enrolled under this part.

5 “(d) TERMS OF APPOINTMENT.—Each member of the
6 Committee shall serve for a term determined appropriate by the
7 Secretary. The terms of service of the members initially ap-
8 pointed shall begin on January 1, 2005.

9 “(e) CHAIRPERSON.—The Secretary shall designate a
10 member of the Committee as Chairperson. The term as Chair-
11 person shall be for a 1-year period.

12 “(f) COMMITTEE PERSONNEL MATTERS.—

13 “(1) MEMBERS.—

14 “(A) COMPENSATION.—Each member of the Com-
15 mittee who is not an officer or employee of the Federal
16 Government shall be compensated at a rate equal to
17 the daily equivalent of the annual rate of basic pay pre-
18 scribed for level IV of the Executive Schedule under
19 section 5315 of title 5, United States Code, for each
20 day (including travel time) during which such member
21 is engaged in the performance of the duties of the
22 Committee. All members of the Committee who are of-
23 ficers or employees of the United States shall serve
24 without compensation in addition to that received for
25 their services as officers or employees of the United
26 States.

27 “(B) TRAVEL EXPENSES.—The members of the
28 Committee shall be allowed travel expenses, including
29 per diem in lieu of subsistence, at rates authorized for
30 employees of agencies under subchapter I of chapter 57
31 of title 5, United States Code, while away from their
32 homes or regular places of business in the performance
33 of services for the Committee.

34 “(2) STAFF.—The Committee may appoint such per-
35 sonnel as the Committee considers appropriate.

36 “(g) OPERATION OF THE COMMITTEE.—



1 “(1) MEETINGS.—The Committee shall meet at the
2 call of the Chairperson (after consultation with the other
3 members of the Committee) not less often than quarterly
4 to consider a specific agenda of issues, as determined by
5 the Chairperson after such consultation.

6 “(2) QUORUM.—Ten members of the Committee shall
7 constitute a quorum for purposes of conducting business.

8 “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section 14
9 of the Federal Advisory Committee Act (5 U.S.C. App.) shall
10 not apply to the Committee.

11 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND AS-
12 SETS.—For purposes of carrying out its duties, the Secretary
13 and the Committee may provide for the transfer to the Com-
14 mittee of such civil service personnel in the employ of the De-
15 partment of Health and Human Services (including the Centers
16 for Medicare & Medicaid Services), and such resources and as-
17 sets of the Department used in carrying out this title, as the
18 Committee requires.

19 “(j) AUTHORIZATION OF APPROPRIATIONS.—There are
20 authorized to be appropriated such sums as may be necessary
21 to carry out the purposes of this section.”.

22 (b) APPLICATION OF GENERAL EXCLUSIONS FROM COV-
23 ERAGE.—

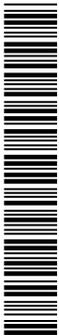
24 (1) APPLICATION TO PART D.—Section 1862(a) (42
25 U.S.C. 1395y(a)) is amended in the matter preceding para-
26 graph (1) by striking “part A or part B” and inserting
27 “part A, B, or D”.

28 (2) PRESCRIPTION MEDICINES NOT EXCLUDED FROM
29 COVERAGE IF APPROPRIATELY PRESCRIBED.—Section
30 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

31 (A) in subparagraph (H), by striking “and” at the
32 end;

33 (B) in subparagraph (I), by striking the semicolon
34 at the end and inserting “, and”; and

35 (C) by adding at the end the following new sub-
36 paragraph:



1 “(J) in the case of prescription medicines covered
2 under part D, which are not prescribed in accordance
3 with such part;”.

4 (c) CONFORMING AMENDMENTS.—(1) Part C of title
5 XVIII is amended—

6 (A) in section 1851(a)(2)(B) (42 U.S.C. 1395w-
7 21(a)(2)(B)), by striking “1859(b)(3)” and inserting
8 “1858(b)(3)”;

9 (B) in section 1851(a)(2)(C) (42 U.S.C. 1395w-
10 21(a)(2)(C)), by striking “1859(b)(2)” and inserting
11 “1858(b)(2)”;

12 (C) in section 1852(a)(1) (42 U.S.C. 1395w-
13 22(a)(1)), by striking “1859(b)(3)” and inserting
14 “1858(b)(3)”;

15 (D) in section 1852(a)(3)(B)(ii) (42 U.S.C. 1395w-
16 22(a)(3)(B)(ii)), by striking “1859(b)(2)(B)” and inserting
17 “1858(b)(2)(B)”;

18 (E) in section 1853(a)(1)(A) (42 U.S.C. 1395w-
19 23(a)(1)(A)), by striking “1859(e)(4)” and inserting
20 “1858(e)(4)”;

21 (F) in section 1853(a)(3)(D) (42 U.S.C. 1395w-
22 23(a)(3)(D)), by striking “1859(e)(4)” and inserting
23 “1858(e)(4)”.

24 (2) Section 1171(a)(5)(D) (42 U.S.C. 1320d(a)(5)(D)) is
25 amended by striking “or (C)” and inserting “(C), or (D)”.

26 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**
27 **SCRIPTION MEDICINE COVERAGE UNDER**
28 **THE MEDICARE+CHOICE PROGRAM.**

29 (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY
30 EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Section
31 1851 (42 U.S.C. 1395w-21) is amended by adding at the end
32 the following new subsection:

33 “(j) AVAILABILITY OF PRESCRIPTION MEDICINE BENE-
34 FITS.—

35 “(1) IN GENERAL.—Notwithstanding any other provi-
36 sion of this part, each Medicare+Choice organization that
37 makes available a Medicare+Choice plan described in sec-



1 tion 1851(a)(2)(A) shall make available such a plan that
2 offers coverage of covered outpatient prescription medicines
3 that is at least actuarially equivalent to the benefits pro-
4 vided under part D. Information respecting such benefits
5 shall be made available in the same manner as information
6 on other benefits provided under this part is made avail-
7 able. Nothing in this paragraph shall be construed as re-
8 quiring the offering of such coverage separate from cov-
9 erage that includes benefits under parts A and B.

10 “(2) TREATMENT OF PRESCRIPTION MEDICINE EN-
11 ROLLEES.—In the case of a Medicare+Choice eligible indi-
12 vidual who is enrolled under part D, the benefits described
13 in paragraph (1) shall be treated in the same manner as
14 benefits described in part B for purposes of coverage and
15 payment and any reference in this part to the Federal Sup-
16 plementary Medical Insurance Trust Fund shall be deemed,
17 with respect to such benefits, to be a reference to the Fed-
18 eral Medicare Prescription Medicine Trust Fund.”.

19 (b) APPLICATION OF QUALITY STANDARDS.—Section
20 1852(e)(2)(A) (42 U.S.C. 1395w-22(e)(2)(A)) is amended—

- 21 (1) by striking “and” at the end of clause (xi);
22 (2) by striking the period at the end of clause (xii)
23 and inserting “, and”; and
24 (3) by adding at the end the following new clause:

25 “(xiii) comply with the standards, and apply
26 the programs, under section 1859B(b) for covered
27 outpatient prescription medicines under the plan.”.

28 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART A
29 AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w-23) is
30 amended—

31 (1) in subsection (a)(1)(A), by striking “and (i)” and
32 inserting “(i), and (j)”; and

33 (2) by adding at the end the following new subsection:

34 “(j) PAYMENT FOR PRESCRIPTION MEDICINE COVERAGE
35 OPTION.—

36 “(1) IN GENERAL.—In the case of a Medicare+Choice
37 plan that provides prescription medicine benefits described



1 in section 1851(j)(1), the amount of payment otherwise
2 made to the Medicare+Choice organization offering the
3 plan shall be increased by the amount described in para-
4 graph (2). Such payments shall be made in the same man-
5 ner and time as the amount otherwise paid, but such
6 amount shall be payable from the Federal Medicare Pre-
7 scription Medicine Trust Fund.

8 “(2) AMOUNT.—The amount described in this para-
9 graph is the monthly Government contribution amount
10 computed under section 1859G(c)(2)(B), but subject to ad-
11 justment under paragraph (3). Such amount shall be uni-
12 form geographically and shall not vary based on the
13 Medicare+Choice payment area involved.

14 “(3) RISK ADJUSTMENT.—The Secretary shall estab-
15 lish a methodology for the adjustment of the payment
16 amount under this subsection in a manner that takes into
17 account the relative risks for use of outpatient prescription
18 medicines by Medicare+Choice enrollees. Such methodology
19 shall be designed in a manner so that the total payments
20 under this title (including part D) are not changed as a re-
21 sult of the application of such methodology.”.

22 (d) SEPARATE APPLICATION OF ADJUSTED COMMUNITY
23 RATE (ACR).—Section 1854 (42 U.S.C. 1395w-24) is amend-
24 ed by adding at the end the following:

25 “(i) APPLICATION TO PRESCRIPTION MEDICINE COV-
26 ERAGE.—The Secretary shall apply the previous provisions of
27 this section (including the computation of the adjusted commu-
28 nity rate) separately with respect to prescription medicine bene-
29 fits described in section 1851(j)(1).”.

30 (f) CONFORMING AMENDMENTS.—

31 (1) Section 1851 (42 U.S.C. 1395w-21) is amended—

32 (A) in subsection (a)(1)(A), by striking “parts A
33 and B” and inserting “parts A, B, and D”; and

34 (B) in subsection (i) by inserting “(and, if applica-
35 ble, part D)” after “parts A and B”.

36 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w-
37 22(a)(1)(A)) is amended by inserting “(and under part D



1 to individuals also enrolled under such part)” after “parts
2 A and B”.

3 (3) Section 1852(d)(1) (42 U.S.C. 1395w-22(d)(1)) is
4 amended—

5 (A) by striking “and” at the end of subparagraph
6 (D);

7 (B) by striking the period at the end of subpara-
8 graph (E) and inserting “; and”; and

9 (C) by adding at the end the following:

10 “(F) the plan for part D benefits guarantees cov-
11 erage of any specifically named prescription medicine
12 for an enrollee to the extent that it would be required
13 to be covered under part D.

14 In carrying out subparagraph (F), a Medicare+Choice or-
15 ganization has the same authority to enter into contracts
16 with respect to coverage of preferred medicines as the Sec-
17 retary has under part D, but subject to an independent
18 contractor appeal or other appeal process that would be ap-
19 plicable to determinations by such a pharmacy contractor
20 consistent with section 1859D(e)(5).”.

21 (e) LIMITATION ON COST-SHARING.—Section 1854(e) (42
22 U.S.C. 1395w-24(e)) is amended by adding at the end the fol-
23 lowing new paragraph:

24 “(5) LIMITATION ON COST-SHARING.—In no event
25 may a Medicare+Choice organization include a require-
26 ment that an enrollee pay cost-sharing in excess of the
27 cost-sharing otherwise permitted under part D.”.

28 **SEC. 103. MEDIGAP REVISIONS.**

29 (a) REQUIRED COVERAGE OF COVERED OUTPATIENT
30 PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42
31 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before “and”
32 at the end the following: “including a requirement that an ap-
33 propriate number of policies provide coverage of medicines
34 which complements but does not duplicate the medicine benefits
35 that beneficiaries are otherwise eligible for benefits under part
36 D of this title (with the Secretary and the National Association
37 of Insurance Commissioners determining the appropriate level



1 of medicine benefits that each benefit package must provide
2 and ensuring that policies providing such coverage are afford-
3 able for beneficiaries;”.

4 (b) EFFECTIVE DATE.—The amendment made by sub-
5 section (a) shall take effect on January 1, 2006.

6 (c) TRANSITION PROVISIONS.—

7 (1) IN GENERAL.—If the Secretary of Health and
8 Human Services identifies a State as requiring a change to
9 its statutes or regulations to conform its regulatory pro-
10 gram to the amendments made by this section, the State
11 regulatory program shall not be considered to be out of
12 compliance with the requirements of section 1882 of the
13 Social Security Act due solely to failure to make such
14 change until the date specified in paragraph (4).

15 (2) NAIC STANDARDS.—If, within 9 months after the
16 date of enactment of this Act, the National Association of
17 Insurance Commissioners (in this subsection referred to as
18 the “NAIC”) modifies its NAIC Model Regulation relating
19 to section 1882 of the Social Security Act (referred to in
20 such section as the 1991 NAIC Model Regulation, as sub-
21 sequently modified) to conform to the amendments made
22 by this section, such revised regulation incorporating the
23 modifications shall be considered to be the applicable NAIC
24 model regulation (including the revised NAIC model regula-
25 tion and the 1991 NAIC Model Regulation) for the pur-
26 poses of such section.

27 (3) SECRETARY STANDARDS.—If the NAIC does not
28 make the modifications described in paragraph (2) within
29 the period specified in such paragraph, the Secretary of
30 Health and Human Services shall make the modifications
31 described in such paragraph and such revised regulation in-
32 corporating the modifications shall be considered to be the
33 appropriate regulation for the purposes of such section.

34 (4) DATE SPECIFIED.—

35 (A) IN GENERAL.—Subject to subparagraph (B),
36 the date specified in this paragraph for a State is the
37 earlier of—



1 (i) the date the State changes its statutes or
2 regulations to conform its regulatory program to
3 the changes made by this section; or

4 (ii) 1 year after the date the NAIC or the Sec-
5 retary first makes the modifications under para-
6 graph (2) or (3), respectively.

7 (B) ADDITIONAL LEGISLATIVE ACTION RE-
8 QUIRED.—In the case of a State which the Secretary
9 identifies as—

10 (i) requiring State legislation (other than leg-
11 islation appropriating funds) to conform its regu-
12 latory program to the changes made in this section;
13 but

14 (ii) having a legislature which is not scheduled
15 to meet in 2004 in a legislative session in which
16 such legislation may be considered;

17 the date specified in this paragraph is the first day of
18 the first calendar quarter beginning after the close of
19 the first legislative session of the State legislature that
20 begins on or after January 1, 2004. For purposes of
21 the previous sentence, in the case of a State that has
22 a 2-year legislative session, each year of such session
23 shall be deemed to be a separate regular session of the
24 State legislature.

25 **SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME**
26 **BENEFICIARIES.**

27 (a) QMB COVERAGE OF PREMIUMS AND COST-SHAR-
28 ING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is
29 amended—

30 (1) in subparagraph (A)—

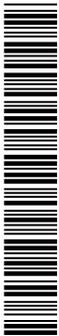
31 (A) by striking “and” at the end of clause (i),

32 (B) by adding “and” at the end of clause (ii), and

33 (C) by adding at the end the following new clause:

34 “(iii) premiums under section 1859D(d).”;

35 (2) in subparagraph (B), by inserting “and section
36 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)” after “1813”; and



1 (3) in subparagraph (C), by striking “and section
2 1833(b)” and inserting “, section 1833(b), and section
3 1859D(c)(2)”.

4 (b) EXPANDED SLMB ELIGIBILITY.—Section
5 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amended—

6 (1) by striking “and” at the end of clause (iii);

7 (2) by adding “and” at the end of clause (iv); and

8 (3) by adding at the end the following new clause:

9 “(v)(I) for making medical assistance available for
10 medicare cost-sharing described in section
11 1905(p)(3)(A)(iii) and medicare cost-sharing described
12 in section 1905(p)(3)(B) and section 1905(p)(3)(C) but
13 only insofar as it relates to benefits provided under
14 part D of title XVIII, subject to section 1905(p)(4), for
15 individuals (other than qualified medicare beneficiaries)
16 who are enrolled under part D of title XVIII and are
17 described in section 1905(p)(1)(B) or would be so de-
18 scribed but for the fact that their income exceeds 100
19 percent, but is less than 150 percent, of the official
20 poverty line (referred to in such section) for a family
21 of the size involved;

22 “(II) subject to section 1905(p)(4), for individuals
23 (other than qualified medicare beneficiaries and individ-
24 uals described in subclause (I)) who are enrolled under
25 part D of title XVIII and would be described in section
26 1905(p)(1)(B) but for the fact that their income ex-
27 ceeds 150 percent, but is less than 175 percent, of the
28 official poverty line (referred to in such section) for a
29 family of the size involved, for making medical assist-
30 ance available for medicare cost-sharing described in
31 section 1905(p)(3)(A)(iii) and medicare cost-sharing
32 described in section 1905(p)(3)(B) and section
33 1905(p)(3)(C) but only insofar as it relates to benefits
34 provided under part D of title XVIII, and the assist-
35 ance for medicare cost-sharing described in section
36 1905(p)(3)(A)(iii) is reduced (on a sliding scale based
37 on income) from 100 percent to 0 percent as the in-



1 come increases from 150 percent to 175 percent of
2 such poverty line;”.

3 (c) FEDERAL FINANCING.—The third sentence of section
4 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting before
5 the period at the end the following: “and with respect to
6 amounts expended that are attributable to section
7 1902(a)(10)(E)(v) (other than for individuals described in sec-
8 tion 1905(p)(1)(B))”.

9 (d) TREATMENT OF TERRITORIES.—

10 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.
11 1396d(p)) is amended—

12 (A) by redesignating paragraphs (5) and (6) as
13 paragraphs (6) and (7), respectively; and

14 (B) by inserting after paragraph (4) the following
15 new paragraph:

16 “(5)(A) In the case of a State, other than the 50 States
17 and the District of Columbia—

18 “(i) the provisions of paragraph (3) insofar as they re-
19 late to section 1859D and the provisions of section
20 1902(a)(10)(E)(v) shall not apply to residents of such
21 State; and

22 “(ii) if the State establishes a plan described in sub-
23 paragraph (B) (for providing medical assistance with re-
24 spect to the provision of prescription medicines to medicare
25 beneficiaries), the amount otherwise determined under sec-
26 tion 1108(f) (as increased under section 1108(g)) for the
27 State shall be increased by the amount specified in sub-
28 paragraph (C).

29 “(B) The plan described in this subparagraph is a plan
30 that—

31 “(i) provides medical assistance with respect to the
32 provision of covered outpatient medicines (as defined in
33 section 1859D(b)) to low-income medicare beneficiaries;
34 and

35 “(ii) assures that additional amounts received by the
36 State that are attributable to the operation of this para-
37 graph are used only for such assistance.



1 “(C)(i) The amount specified in this subparagraph for a
2 State for a year is equal to the product of—

3 “(I) the aggregate amount specified in clause (ii); and

4 “(II) the amount specified in section 1108(g)(1) for
5 that State, divided by the sum of the amounts specified in
6 such section for all such States.

7 “(ii) The aggregate amount specified in this clause for—

8 “(I) 2006, is equal to \$25,000,000; or

9 “(II) a subsequent year, is equal to the aggregate
10 amount specified in this clause for the previous year in-
11 creased by annual percentage increase specified in section
12 1859D(c)(8)(B) for the year involved.

13 “(D) The Secretary shall submit to Congress a report on
14 the application of this paragraph and may include in the report
15 such recommendations as the Secretary deems appropriate.”

16 (2) CONFORMING AMENDMENT.—Section 1108(f) (42
17 U.S.C. 1308(f)) is amended by inserting “and section
18 1905(p)(5)(A)(ii)” after “Subject to subsection (g)”.

19 (e) APPLICATION OF COST-SHARING.—Section 1902(n)(2)
20 (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the
21 following: “The previous sentence shall not apply to medicare
22 cost-sharing relating to benefits under part D of title XVIII.”

23 (f) EFFECTIVE DATE.—The amendments made by this
24 section apply to medical assistance for premiums and cost-shar-
25 ing incurred on or after January 1, 2006, with regard to
26 whether regulations to implement such amendments are pro-
27 mulgated by such date.

28 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**
29 **MEDICARE PAYMENT ADVISORY COMMIS-**
30 **SION (MEDPAC).**

31 (a) EXPANSION OF MEMBERSHIP.—

32 (1) IN GENERAL.—Section 1805(c) (42 U.S.C. 1395b-
33 6(c)) is amended—

34 (A) in paragraph (1), by striking “17” and insert-
35 ing “19”; and



1 (B) in paragraph (2)(B), by inserting “experts in
2 the area of pharmacology and prescription medicine
3 benefit programs,” after “other health professionals.”

4 (2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

5 (A) IN GENERAL.—For purposes of staggering the
6 initial terms of members of the Medicare Payment Ad-
7 visory Commission under section 1805(c)(3) of the So-
8 cial Security Act (42 U.S.C. 1395b–6(c)(3)), the initial
9 terms of the 2 additional members of the Commission
10 provided for by the amendment under paragraph (1)(A)
11 are as follows:

12 (i) One member shall be appointed for 1 year.

13 (ii) One member shall be appointed for 2
14 years.

15 (B) COMMENCEMENT OF TERMS.—Such terms
16 shall begin on January 1, 2004.

17 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42
18 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the
19 following new subparagraph:

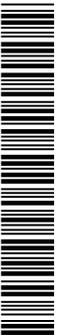
20 “(D) PRESCRIPTION MEDICINE BENEFIT PRO-
21 GRAM.—Specifically, the Commission shall review, with
22 respect to the prescription medicine benefit program
23 under part D, the following:

24 “(i) The methodologies used for the manage-
25 ment of costs and utilization of prescription medi-
26 cines.

27 “(ii) The prices negotiated and paid, including
28 trends in such prices and applicable discounts and
29 comparisons with prices under section
30 1859E(a)(2)(E).

31 “(iii) The relationship of pharmacy acquisition
32 costs to the prices so negotiated and paid.

33 “(iv) The methodologies used to ensure access
34 to covered outpatient prescription medicines and to
35 ensure quality in the appropriate dispensing and
36 utilization of such medicines.



1 “(v) The impact of the program on promoting
2 the development of breakthrough medicines.”.

3 **SEC. 106. STATE PHARMACEUTICAL ASSISTANCE TRAN-**
4 **SITION COMMISSION.**

5 (a) ESTABLISHMENT.—

6 (1) IN GENERAL.—There is established, as of the first
7 day of the third month beginning after the date of the en-
8 actment of this Act, a State Pharmaceutical Assistance
9 Transition Commission (in this section referred to as the
10 “Commission”) to develop a proposal for addressing the
11 unique transitional issues facing State pharmaceutical as-
12 sistance programs, and program participants, due to the
13 implementation of the medicare prescription drug program
14 under part D of title XVIII of the Social Security Act.

15 (2) DEFINITIONS.—For purposes of this section:

16 (A) STATE PHARMACEUTICAL ASSISTANCE PRO-
17 GRAM DEFINED.—The term “State pharmaceutical as-
18 sistance program” means a program (other than the
19 medicaid program) operated by a State (or under con-
20 tract with a State) that provides as of the date of the
21 enactment of this Act assistance to low-income medi-
22 care beneficiaries for the purchase of prescription
23 drugs.

24 (B) PROGRAM PARTICIPANT.—The term “program
25 participant” means a low-income medicare beneficiary
26 who is a participant in a State pharmaceutical assist-
27 ance program.

28 (b) COMPOSITION.—The Commission shall include the fol-
29 lowing:

30 (1) A representative of each governor of each State
31 that the Secretary identifies as operating on a statewide
32 basis a State pharmaceutical assistance program that pro-
33 vides for eligibility and benefits that are comparable or
34 more generous than the low-income assistance eligibility
35 and benefits offered under part D of title XVIII of the So-
36 cial Security Act.



1 (2) Representatives from other States that the Sec-
2 retary identifies have in operation other State pharma-
3 ceutical assistance programs, as appointed by the Sec-
4 retary.

5 (3) Representatives of organizations that have an in-
6 herent interest in program participants or the program
7 itself, as appointed by the Secretary but not to exceed the
8 number of representatives under paragraphs (1) and (2).

9 (4) Representatives of Medicare+Choice organizations
10 and other private health insurance plans, as appointed by
11 the Secretary.

12 (5) The Secretary (or the Secretary's designee) and
13 such other members as the Secretary may specify
14 The Secretary shall designate a member to serve as chair of
15 the Commission and the Commission shall meet at the call of
16 the chair.

17 (c) DEVELOPMENT OF PROPOSAL.—The Commission shall
18 develop the proposal described in subsection (a) in a manner
19 consistent with the following principles:

20 (1) Protection of the interests of program participants
21 in a manner that is the least disruptive to such participants
22 and that includes a single point of contact for enrollment
23 and processing of benefits.

24 (2) Protection of the financial and flexibility interests
25 of States so that States are not financially worse off as a
26 result of the enactment of this title.

27 (3) Principles of medicare modernization provided
28 under title II of this Act.

29 (d) REPORT.—By not later than January 1, 2005, the
30 Commission shall submit to the President and the Congress a
31 report that contains a detailed proposal (including specific leg-
32 islative or administrative recommendations, if any) and such
33 other recommendations as the Commission deems appropriate.

34 (e) SUPPORT.—The Secretary shall provide the Commis-
35 sion with the administrative support services necessary for the
36 Commission to carry out its responsibilities under this section.



1 (f) TERMINATION.—The Commission shall terminate 30
2 days after the date of submission of the report under sub-
3 section (d).

4 **TITLE II—MEDICARE+CHOICE**

5 **SEC. 201. MEDICARE+CHOICE IMPROVEMENTS.**

6 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

7 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
8 1395w-23(c)(1)) is amended by adding at the end the fol-
9 lowing:

10 “(D) BASED ON 100 PERCENT OF FEE-FOR-SERV-
11 ICE COSTS.—

12 “(i) IN GENERAL.—For 2004, the adjusted av-
13 erage per capita cost for the year involved, deter-
14 mined under section 1876(a)(4) for the
15 Medicare+Choice payment area for services cov-
16 ered under parts A and B for individuals entitled
17 to benefits under part A and enrolled under part
18 B who are not enrolled in a Medicare+Choice
19 under this part for the year, but adjusted to ex-
20 clude costs attributable to payments under section
21 1886(h).

22 “(ii) INCLUSION OF COSTS OF VA AND DOD
23 MILITARY FACILITY SERVICES TO MEDICARE-ELIGI-
24 BLE BENEFICIARIES.—In determining the adjusted
25 average per capita cost under clause (i) for a year,
26 such cost shall be adjusted to include the Sec-
27 retary’s estimate, on a per capita basis, of the
28 amount of additional payments that would have
29 been made in the area involved under this title if
30 individuals entitled to benefits under this title had
31 not received services from facilities of the Depart-
32 ment of Veterans Affairs or the Department of De-
33 fense.”.

34 (2) CONFORMING AMENDMENT.—Such section is fur-
35 ther amended, in the matter before subparagraph (A), by
36 striking “or (C)” and inserting “(C), or (D)”.



1 (b) REVISION OF BLEND.—

2 (1) REVISION OF NATIONAL AVERAGE USED IN CAL-
3 CULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42
4 U.S.C. 1395w-23(c)(4)(B)(i)(II)) is amended by inserting
5 “who (with respect to determinations for 2004) are enrolled
6 in a Medicare+Choice plan” after “the average number of
7 medicare beneficiaries”.

8 (2) CHANGE IN BUDGET NEUTRALITY.—Section
9 1853(c) (42 U.S.C. 1395w-23(c)) is amended—

10 (A) in paragraph (1)(A), by inserting “(for a year
11 before 2004)” after “multiplied”; and

12 (B) in paragraph (5), by inserting “(before 2004)”
13 after “for each year”.

14 (c) INCREASING MINIMUM PERCENTAGE INCREASE TO
15 NATIONAL GROWTH RATE.—

16 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
17 1395w-23(c)(1)) is amended—

18 (A) in subparagraph (B)(iv), by striking “and
19 each succeeding year” and inserting “, 2003, and
20 2004”;

21 (B) in subparagraph (C)(iv), by striking “and each
22 succeeding year” and inserting “and 2003”; and

23 (C) by adding at the end of subparagraph (C) the
24 following new clause:

25 “(v) For 2004 and each succeeding year, the
26 greater of—

27 “(I) 102 percent of the annual
28 Medicare+Choice capitation rate under this
29 paragraph for the area for the previous year; or

30 “(II) the annual Medicare+Choice capita-
31 tion rate under this paragraph for the area for
32 the previous year increased by the national per
33 capita Medicare+Choice growth percentage, de-
34 scribed in paragraph (6) for that succeeding
35 year, but not taking into account any adjust-
36 ment under paragraph (6)(C) for a year before
37 2004.”.



1 (2) CONFORMING AMENDMENT.—Section
2 1853(c)(6)(C) (42 U.S.C. 1395w-23(c)(6)(C)) is amended
3 by inserting before the period at the end the following: “,
4 except that for purposes of paragraph (1)(C)(v)(II), no
5 such adjustment shall be made for a year before 2004”.

6 (d) INCLUSION OF COSTS OF DOD AND VA MILITARY FA-
7 CILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN
8 CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—
9 Section 1853(c)(3) (42 U.S.C. 1395w-23(c)(3)) is amended—

10 (1) in subparagraph (A), by striking “subparagraph
11 (B)” and inserting “subparagraphs (B) and (E)”, and

12 (2) by adding at the end the following new subpara-
13 graph:

14 “(E) INCLUSION OF COSTS OF DOD AND VA MILI-
15 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
16 BENEFICIARIES.—In determining the area-specific
17 Medicare+Choice capitation rate under subparagraph
18 (A) for a year (beginning with 2004), the annual per
19 capita rate of payment for 1997 determined under sec-
20 tion 1876(a)(1)(C) shall be adjusted to include in the
21 rate the Secretary’s estimate, on a per capita basis, of
22 the amount of additional payments that would have
23 been made in the area involved under this title if indi-
24 viduals entitled to benefits under this title had not re-
25 ceived services from facilities of the Department of De-
26 fense or the Department of Veterans Affairs.”.

27 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT
28 HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

29 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
30 1395w-23(g)) is amended—

31 (A) by inserting “or from a rehabilitation facility
32 (as defined in section 1886(j)(1)(A))” after
33 “1886(d)(1)(B)”; and

34 (B) in paragraph (2)(B), by inserting “or section
35 1886(j), as the case may be,” after “1886(d)”.



1 (2) EFFECTIVE DATE.—The amendments made by
2 paragraph (1) shall apply to contract years beginning on or
3 after January 1, 2004.

4 (f) MEDPAC STUDY OF AAPCC.—

5 (1) STUDY.—The Medicare Payment Advisory Com-
6 mission shall conduct a study that assesses the method
7 used for determining the adjusted average per capita cost
8 (AAPCC) under section 1876(a)(4) of the Social Security
9 Act (42 U.S.C. 1395mm(a)(4)) as applied under section
10 1853(c)(1)(A) of such Act (as amended by subsection (a)).
11 Such study shall include an examination of—

12 (A) the bases for variation in such costs between
13 different areas, including differences in input prices,
14 utilization, and practice patterns;

15 (B) the appropriate geographic area for payment
16 under the Medicare+Choice program under part C of
17 title XVIII of such Act; and

18 (C) the accuracy of risk adjustment methods in re-
19 flecting differences in costs of providing care to dif-
20 ferent groups of beneficiaries served under such pro-
21 gram.

22 (2) REPORT.—Not later than 18 months after the
23 date of the enactment of this Act, the Commission shall
24 submit to Congress a report on the study conducted under
25 paragraph (1).

26 (g) REPORT ON IMPACT OF INCREASED FINANCIAL AS-
27 SISTANCE TO MEDICARE+CHOICE PLANS.—Not later than
28 July 1, 2006, the Medicare Benefits Administrator shall submit
29 to Congress a report that describes the impact of additional fi-
30 nancing provided under this Act and other Acts (including the
31 Medicare, Medicaid, and SCHIP Balanced Budget Refinement
32 Act of 1999 and BIPA) on the availability of Medicare+Choice
33 plans in different areas and its impact on lowering premiums
34 and increasing benefits under such plans.

35 (h) LIMITATION ON APPLICATION TO 2004 AND 2005.—
36 Notwithstanding any other provision of law, the amendments
37 made by this section shall only apply to payment rates for 2004



1 and 2005 and for subsequent years the payment shall be made
2 on the basis of law as in effect before the date of the enactment
3 of this Act.

4 **SEC. 202. MAKING PERMANENT CHANGE IN**
5 **MEDICARE+CHOICE REPORTING DEADLINES**
6 **AND ANNUAL, COORDINATED ELECTION PE-**
7 **RIOD.**

8 (a) CHANGE IN REPORTING DEADLINE.—Section
9 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by sec-
10 tion 532(b)(1) of the Public Health Security and Bioterrorism
11 Preparedness and Response Act of 2002, is amended by strik-
12 ing “2002, 2003, and 2004 (or July 1 of each other year)” and
13 inserting “2002 and each subsequent year”.

14 (b) DELAY IN ANNUAL, COORDINATED ELECTION PE-
15 RIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)),
16 as amended by section 532(c)(1)(A) of the Public Health Secu-
17 rity and Bioterrorism Preparedness and Response Act of 2002,
18 is amended—

19 (1) by striking “and after 2005”; and

20 (2) by striking “, 2004, and 2005” and inserting “and
21 any subsequent year”.

22 (c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Sec-
23 tion 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by
24 section 532(d)(1) of the Public Health Security and Bioter-
25 rorism Preparedness and Response Act of 2002, is amended—

26 (1) by striking “and after 2005”; and

27 (2) by striking “and 2005” and inserting “and each
28 subsequent year”.

29 **SEC. 203. SPECIALIZED MEDICARE+CHOICE PLANS FOR**
30 **SPECIAL NEEDS BENEFICIARIES.**

31 (a) TREATMENT AS COORDINATED CARE PLAN.—Section
32 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by
33 adding at the end the following new sentence: “Specialized
34 Medicare+Choice plans for special needs beneficiaries (as de-
35 fined in section 1859(b)(4)) may be any type of coordinated
36 care plan.”.

37 (b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPECIAL
38 NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42



1 U.S.C. 1395w-29(b)) is amended by adding at the end the fol-
2 lowing new paragraph:

3 “(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR
4 SPECIAL NEEDS BENEFICIARIES.—

5 “(A) IN GENERAL.—The term ‘specialized
6 Medicare+Choice plan for special needs beneficiaries’
7 means a Medicare+Choice plan that exclusively serves
8 special needs beneficiaries (as defined in subparagraph
9 (B)).

10 “(B) SPECIAL NEEDS BENEFICIARY.—The term
11 ‘special needs beneficiary’ means a Medicare+Choice
12 eligible individual who—

13 “(i) is institutionalized (as defined by the Sec-
14 retary);

15 “(ii) is entitled to medical assistance under a
16 State plan under title XIX; or

17 “(iii) meets such requirements as the Sec-
18 retary may determine would benefit from enroll-
19 ment in such a specialized Medicare+Choice plan
20 described in subparagraph (A) for individuals with
21 severe or disabling chronic conditions.”.

22 (c) RESTRICTION ON ENROLLMENT PERMITTED.—Section
23 1859 (42 U.S.C. 1395w-29) is amended by adding at the end
24 the following new subsection:

25 “(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED
26 MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENE-
27 FICIARIES.—In the case of a specialized Medicare+Choice plan
28 (as defined in subsection (b)(4)), notwithstanding any other
29 provision of this part and in accordance with regulations of the
30 Secretary and for periods before January 1, 2007, the plan
31 may restrict the enrollment of individuals under the plan to in-
32 dividuals who are within one or more classes of special needs
33 beneficiaries.”.

34 (d) REPORT TO CONGRESS.—Not later than December 31,
35 2005, the Medicare Benefits Administrator shall submit to
36 Congress a report that assesses the impact of specialized
37 Medicare+Choice plans for special needs beneficiaries on the



1 cost and quality of services provided to enrollees. Such report
2 shall include an assessment of the costs and savings to the
3 medicare program as a result of amendments made by sub-
4 sections (a), (b), and (c).

5 (e) EFFECTIVE DATES.—

6 (1) IN GENERAL.—The amendments made by sub-
7 sections (a), (b), and (c) shall take effect upon the date of
8 the enactment of this Act.

9 (2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR
10 SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later
11 than 6 months after the date of the enactment of this Act,
12 the Secretary of Health and Human Services shall issue
13 final regulations to establish requirements for special needs
14 beneficiaries under section 1859(b)(4)(B)(iii) of the Social
15 Security Act, as added by subsection (b).

16 **SEC. 204. MEDICARE MSAS.**

17 Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amend-
18 ed by inserting “or with an organization offering a MSA plan”
19 after “section 1851(a)(2)(A)”.

20 **SEC. 205. EXTENSION OF REASONABLE COST CON-**
21 **TRACTS.**

22 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
23 1395mm(h)(5)) is amended to read as follows:

24 “(C)(i) Subject to clause (ii), may be extended or renewed
25 under this subsection indefinitely.

26 “(ii) For any period beginning on or after January 1,
27 2008, a reasonable cost reimbursement contract under this sub-
28 section may not be extended or renewed for a service area inso-
29 far as such area, during the entire previous year, was within
30 the service area of 2 or more plans which were coordinated care
31 Medicare+Choice plans under part C or 2 or more enhanced
32 fee-for-service plans under part E and each of which plan for
33 that previous year for the area involved meets the following
34 minimum enrollment requirements:

35 “(I) With respect to any portion of the area involved
36 that is within a Metropolitan Statistical Area with a popu-



1 lation of more than 250,000 and counties contiguous to
2 such Metropolitan Statistical Area, 5,000 individuals.
3 “(II) With respect to any other portion of such area,
4 1,500 individuals.”

5 **SEC. 206. EXTENSION OF MUNICIPAL HEALTH SERVICE**
6 **DEMONSTRATION PROJECTS.**

7 The last sentence of section 9215(a) of the Consolidated
8 Omnibus Budget Reconciliation Act of 1985 (42 U.S.C.
9 1395b–1 note), as previously amended, is amended by striking
10 “December 31, 2004, but only with respect to” and all that fol-
11 lows and inserting “December 31, 2009, but only with respect
12 to individuals who reside in the city in which the project is op-
13 erated and so long as the total number of individuals partici-
14 pating in the project does not exceed the number of such indi-
15 viduals participating as of January 1, 1996.”

16 **TITLE III—COMBATTING WASTE,**
17 **FRAUD, AND ABUSE**

18 **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-**
19 **SIONS.**

20 (a) TECHNICAL AMENDMENT CONCERNING SECRETARY’S
21 AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CER-
22 TAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

23 (1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C.
24 1395y(b)(2)) is amended—

25 (A) in subparagraph (A)(ii), by striking “promptly
26 (as determined in accordance with regulations)”;

27 (B) in subparagraph (B)—

28 (i) by redesignating clauses (i) through (iii) as
29 clauses (ii) through (iv), respectively; and

30 (ii) by inserting before clause (ii), as so redesi-
31 gnated, the following new clause:

32 “(i) AUTHORITY TO MAKE CONDITIONAL PAY-
33 MENT.—The Secretary may make payment under
34 this title with respect to an item or service if a pri-
35 mary plan described in subparagraph (A)(ii) has
36 not made or cannot reasonably be expected to make
37 payment with respect to such item or service



1 promptly (as determined in accordance with regula-
2 tions). Any such payment by the Secretary shall be
3 conditioned on reimbursement to the appropriate
4 Trust Fund in accordance with the succeeding pro-
5 visions of this subsection.”.

6 (2) EFFECTIVE DATE.—The amendments made by
7 paragraph (1) shall be effective as if included in the enact-
8 ment of title III of the Medicare and Medicaid Budget Rec-
9 onciliation Amendments of 1984 (Public Law 98-369).

10 (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAY-
11 MENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
12 1395y(b)(2)) is further amended—

13 (1) in subparagraph (A), in the matter following
14 clause (ii), by inserting the following sentence at the end:
15 “An entity that engages in a business, trade, or profession
16 shall be deemed to have a self-insured plan if it carries its
17 own risk (whether by a failure to obtain insurance, or oth-
18 erwise) in whole or in part.”;

19 (2) in subparagraph (B)(ii), as redesignated by sub-
20 section (a)(2)(B)—

21 (A) by striking the first sentence and inserting the
22 following: “A primary plan, and an entity that receives
23 payment from a primary plan, shall reimburse the ap-
24 propriate Trust Fund for any payment made by the
25 Secretary under this title with respect to an item or
26 service if it is demonstrated that such primary plan has
27 or had a responsibility to make payment with respect
28 to such item or service. A primary plan’s responsibility
29 for such payment may be demonstrated by a judgment,
30 a payment conditioned upon the recipient’s com-
31 promise, waiver, or release (whether or not there is a
32 determination or admission of liability) of payment for
33 items or services included in a claim against the pri-
34 mary plan or the primary plan’s insured, or by other
35 means.”; and

36 (B) in the final sentence, by striking “on the date
37 such notice or other information is received” and in-



1 serting “on the date notice of, or information related
2 to, a primary plan’s responsibility for such payment or
3 other information is received”; and

4 (3) in subparagraph (B)(iii), , as redesignated by sub-
5 section (a)(2)(B), by striking the first sentence and insert-
6 ing the following: “In order to recover payment made under
7 this title for an item or service, the United States may
8 bring an action against any or all entities that are or were
9 required or responsible (directly, as an insurer or self-in-
10 surer, as a third-party administrator, as an employer that
11 sponsors or contributes to a group health plan, or large
12 group health plan, or otherwise) to make payment with re-
13 spect to the same item or service (or any portion thereof)
14 under a primary plan. The United States may, in accord-
15 ance with paragraph (3)(A) collect double damages against
16 any such entity. In addition, the United States may recover
17 under this clause from any entity that has received pay-
18 ment from a primary plan or from the proceeds of a pri-
19 mary plan’s payment to any entity.”.

20 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C.
21 1395y(b)) is amended—

22 (1) in paragraph (1)(A), by moving the indentation of
23 clauses (ii) through (v) 2 ems to the left; and

24 (2) in paragraph (3)(A), by striking “such” before
25 “paragraphs”.

26 **SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN**
27 **ITEMS AND SERVICES.**

28 (a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3) is
29 amended to read as follows:

30 “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

31 “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE AC-
32 QUISITION PROGRAMS.—

33 “(1) IMPLEMENTATION OF PROGRAMS.—

34 “(A) IN GENERAL.—The Secretary shall establish
35 and implement programs under which competitive ac-
36 quisition areas are established throughout the United
37 States for contract award purposes for the furnishing



1 under this part of competitively priced items and serv-
2 ices (described in paragraph (2)) for which payment is
3 made under this part. Such areas may differ for dif-
4 ferent items and services.

5 “(B) PHASED-IN IMPLEMENTATION.—The pro-
6 grams shall be phased-in—

7 “(i) among competitive acquisition areas over
8 a period of not longer than 3 years in a manner
9 so that the competition under the programs occurs
10 in—

11 “(I) at least $\frac{1}{3}$ of such areas in 2009; and

12 “(II) at least $\frac{2}{3}$ of such areas in 2010;

13 and

14 “(ii) among items and services in a manner
15 such that the programs apply to the highest cost
16 and highest volume items and services first.

17 “(C) WAIVER OF CERTAIN PROVISIONS.—In car-
18 rying out the programs, the Secretary may waive such
19 provisions of the Federal Acquisition Regulation as are
20 necessary for the efficient implementation of this sec-
21 tion, other than provisions relating to confidentiality of
22 information and such other provisions as the Secretary
23 determines appropriate.

24 “(2) ITEMS AND SERVICES DESCRIBED.—The items
25 and services referred to in paragraph (1) are the following:

26 “(A) DURABLE MEDICAL EQUIPMENT AND MED-
27 ICAL SUPPLIES.—Covered items (as defined in section
28 1834(a)(13)) for which payment is otherwise made
29 under section 1834(a), including items used in infusion
30 and drugs and supplies used in conjunction with dura-
31 ble medical equipment, but excluding class III devices
32 under the Federal Food, Drug, and Cosmetic Act.

33 “(B) OTHER EQUIPMENT AND SUPPLIES.—Items,
34 equipment, and supplies (as described in section
35 1842(s)(2)(D) other than enteral nutrients).

36 “(C) OFF-THE-SHELF ORTHOTICS.—Orthotics (de-
37 scribed in section 1861(s)(9)) for which payment is



1 otherwise made under section 1834(h) which require
2 minimal self-adjustment for appropriate use and does
3 not require expertise in trimming, bending, molding,
4 assembling, or customizing to fit to the patient.

5 “(3) EXCEPTION AUTHORITY.—In carrying out the
6 programs under this section, the Secretary may exempt—

7 “(A) rural areas and areas with low population
8 density within urban areas that are not competitive,
9 unless there is a significant national market through
10 mail order for a particular item or service; and

11 “(B) items and services for which the application
12 of competitive acquisition is not likely to result in sig-
13 nificant savings.

14 “(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF
15 DURABLE MEDICAL EQUIPMENT.—In the case of a covered
16 item for which payment is made on a rental basis under
17 section 1834(a), the Secretary shall establish a process by
18 which rental agreements for the covered items entered into
19 before the application of the competitive acquisition pro-
20 gram under this section for the item may be continued not-
21 withstanding this section. In the case of any such continu-
22 ation, the supplier involved shall provide for appropriate
23 servicing and replacement, as required under section
24 1834(a).

25 “(5) PHYSICIAN AUTHORIZATION.—The Secretary may
26 establish a process under which a physician may prescribe
27 a particular brand or mode of delivery of an item or service
28 if the item or service involved is clinically more appropriate
29 than other similar items or services.

30 “(6) APPLICATION.—For each competitive acquisition
31 area in which the program is implemented under this sub-
32 section with respect to items and services, the payment
33 basis determined under the competition conducted under
34 subsection (b) shall be substituted for the payment basis
35 otherwise applied under section 1834(a).

36 “(b) PROGRAM REQUIREMENTS.—



1 “(1) IN GENERAL.—The Secretary shall conduct a
2 competition among entities supplying items and services de-
3 scribed in subsection (a)(2) for each competitive acquisition
4 area in which the program is implemented under subsection
5 (a) with respect to such items and services.

6 “(2) CONDITIONS FOR AWARDING CONTRACT.—

7 “(A) IN GENERAL.—The Secretary may not award
8 a contract to any entity under the competition con-
9 ducted in an competitive acquisition area pursuant to
10 paragraph (1) to furnish such items or services unless
11 the Secretary finds all of the following:

12 “(i) The entity meets quality and financial
13 standards specified by the Secretary or developed
14 by the Program Advisory and Oversight Committee
15 established under subsection (c).

16 “(ii) The total amounts to be paid under the
17 contract (including costs associated with the ad-
18 ministration of the contract) are expected to be less
19 than the total amounts that would otherwise be
20 paid.

21 “(iii) Beneficiary access to a choice of multiple
22 suppliers in the area is maintained.

23 “(iv) Beneficiary liability is limited to 20 per-
24 cent of the applicable contract award price, except
25 in such cases where a supplier has furnished an up-
26 graded item and has executed an advanced bene-
27 ficiary notice.

28 “(B) DEVELOPMENT OF QUALITY STANDARDS FOR
29 DME PRODUCTS.—

30 “(i) IN GENERAL.—The quality standards
31 specified under subparagraph (A)(i) shall not be
32 less than the quality standards that would other-
33 wise apply if this section did not apply and shall
34 include consumer services standards. Not later than
35 July 1, 2007, the Secretary shall establish new
36 quality standards for products subject to competi-
37 tive acquisition under this section. Such standards



1 shall be applied prospectively and shall be published
2 on the website of the Department of Health and
3 Human Services.

4 “(ii) CONSULTATION WITH PROGRAM ADVI-
5 SORY AND OVERSIGHT COMMITTEE.—The Secretary
6 shall consult with the Program Advisory and Over-
7 sight Committee (established under subsection (c))
8 to review (and advise the Secretary concerning) the
9 quality standards referred to in clause (i).

10 “(3) CONTENTS OF CONTRACT.—

11 “(A) IN GENERAL.—A contract entered into with
12 an entity under the competition conducted pursuant to
13 paragraph (1) is subject to terms and conditions that
14 the Secretary may specify.

15 “(B) TERM OF CONTRACTS.—The Secretary shall
16 recompile contracts under this section not less often
17 than once every 3 years.

18 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

19 “(A) IN GENERAL.—The Secretary may limit the
20 number of contractors in a competitive acquisition area
21 to the number needed to meet projected demand for
22 items and services covered under the contracts. In
23 awarding contracts, the Secretary shall take into ac-
24 count the ability of bidding entities to furnish items or
25 services in sufficient quantities to meet the anticipated
26 needs of beneficiaries for such items or services in the
27 geographic area covered under the contract on a timely
28 basis.

29 “(B) MULTIPLE WINNERS.—The Secretary shall
30 award contracts to multiple entities submitting bids in
31 each area for an item or service.

32 “(5) PAYMENT.—Payment under this part for com-
33 petitively priced items and services described in subsection
34 (a)(2) shall be based on the bids submitted and accepted
35 under this section for such items and services.

36 “(6) PARTICIPATING CONTRACTORS.—Payment shall
37 not be made for items and services described in subsection



1 (a)(2) furnished by a contractor and for which competition
2 is conducted under this section unless—

3 “(A) the contractor has submitted a bid for such
4 items and services under this section; and

5 “(B) the Secretary has awarded a contract to the
6 contractor for such items and services under this sec-
7 tion.

8 In this section, the term ‘bid’ means a request for a pro-
9 posal for an item or service that includes the cost of the
10 item or service, and where appropriate, any services that
11 are attendant to the provision of the item or service.

12 “(7) CONSIDERATION IN DETERMINING CATEGORIES
13 FOR BIDS.—The Secretary shall consider the similarity of
14 the clinical efficiency and value of specific codes and prod-
15 ucts, including products that may provide a therapeutic ad-
16 vantage to beneficiaries, before delineating the categories
17 and products that will be subject to bidding.

18 “(8) AUTHORITY TO CONTRACT FOR EDUCATION, MON-
19 ITORING, OUTREACH AND COMPLAINT SERVICES.—The Sec-
20 retary may enter into a contract with an appropriate entity
21 to address complaints from beneficiaries who receive items
22 and services from an entity with a contract under this sec-
23 tion and to conduct appropriate education of and outreach
24 to such beneficiaries and monitoring quality of services with
25 respect to the program.

26 “(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

27 “(1) ESTABLISHMENT.—There is established a Pro-
28 gram Advisory and Oversight Committee (hereinafter in
29 this section referred to as the ‘Committee’).

30 “(2) MEMBERSHIP; TERMS.—The Committee shall
31 consist of such members as the Secretary may appoint who
32 shall serve for such term as the Secretary may specify.

33 “(3) DUTIES.—

34 “(A) TECHNICAL ASSISTANCE.—The Committee
35 shall provide advice and technical assistance to the Sec-
36 retary with respect to the following functions:



1 “(i) The implementation of the program under
2 this section.

3 “(ii) The establishment of requirements for
4 collection of data.

5 “(iii) The development of proposals for effi-
6 cient interaction among manufacturers and dis-
7 tributors of the items and services and providers
8 and beneficiaries.

9 “(B) ADDITIONAL DUTIES.—The Committee shall
10 perform such additional functions to assist the Sec-
11 retary in carrying out this section as the Secretary may
12 specify.

13 “(4) INAPPLICABILITY OF FACa.—The provisions of
14 the Federal Advisory Committee Act (5 U.S.C. App.) shall
15 not apply.

16 “(d) ANNUAL REPORTS.—The Secretary shall submit to
17 Congress an annual management report on the programs under
18 this section. Each such report shall include information on sav-
19 ings, reductions in beneficiary cost-sharing, access to and qual-
20 ity of items and services, and beneficiary satisfaction.

21 “(e) DEMONSTRATION PROJECT FOR CLINICAL LABORA-
22 TORY SERVICES.—

23 “(1) IN GENERAL.—The Secretary shall conduct a
24 demonstration project on the application of competitive ac-
25 quisition under this section to clinical diagnostic laboratory
26 tests—

27 “(A) for which payment is otherwise made under
28 section 1833(h) or 1834(d)(1) (relating to colorectal
29 cancer screening tests); and

30 “(B) which are furnished by entities that did not
31 have a face-to-face encounter with the individual.

32 “(2) TERMS AND CONDITIONS.—Such project shall be
33 under the same conditions as are applicable to items and
34 services described in subsection (a)(2).

35 “(3) REPORT.—The Secretary shall submit to
36 Congress—



1 “(A) an initial report on the project not later than
2 December 31, 2008; and

3 “(B) such progress and final reports on the
4 project after such date as the Secretary determines ap-
5 propriate.”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF
8 INHERENT REASONABLENESS AUTHORITY.—Section
9 1834(a) (42 U.S.C. 1395m(a)) is amended—

10 (A) in paragraph (1)(B), by striking “The pay-
11 ment basis” and inserting “Subject to subparagraph
12 (E)(i), the payment basis”;

13 (B) in paragraph (1)(C), by striking “This sub-
14 section” and inserting “Subject to subparagraph
15 (E)(ii), this subsection”;

16 (C) by adding at the end of paragraph (1) the fol-
17 lowing new subparagraph:

18 “(E) APPLICATION OF COMPETITIVE ACQUISITION;
19 ELIMINATION OF INHERENT REASONABLENESS AU-
20 THORITY.—In the case of covered items and services
21 that are included in a competitive acquisition program
22 in a competitive acquisition area under section
23 1847(a)—

24 “(i) the payment basis under this subsection
25 for such items and services furnished in such area
26 shall be the payment basis determined under such
27 competitive acquisition program; and

28 “(ii) the Secretary may use information on the
29 payment determined under such competitive acqui-
30 sition programs to adjust the payment amount oth-
31 erwise recognized under subparagraph (B)(ii) for
32 an area that is not a competitive acquisition area
33 under section 1847 and in the case of such adjust-
34 ment, paragraph (10)(B) shall not be applied.”;
35 and

36 (D) in paragraph (10)(B), by inserting “in an
37 area and with respect to covered items and services for



1 which the Secretary does not make a payment amount
2 adjustment under paragraph (1)(E)” after “under this
3 subsection”.

4 (2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF IN-
5 HERENT REASONABLENESS AUTHORITY.—Section 1834(h)
6 (42 U.S.C. 1395m(h)) is amended—

7 (A) in paragraph (1)(B), by striking “and (E)”
8 and inserting “, (E) , and (H)(i)”;

9 (B) in paragraph (1)(D), by striking “This sub-
10 section” and inserting “Subject to subparagraph
11 (H)(ii), this subsection”;

12 (C) by adding at the end of paragraph (1) the fol-
13 lowing new subparagraph:

14 “(H) APPLICATION OF COMPETITIVE ACQUISITION
15 TO ORTHOTICS; ELIMINATION OF INHERENT REASON-
16 ABLENESS AUTHORITY.—In the case of orthotics de-
17 scribed in paragraph (2)(B) of section 1847(a) that are
18 included in a competitive acquisition program in a com-
19 petitive acquisition area under such section—

20 “(i) the payment basis under this subsection
21 for such orthotics furnished in such area shall be
22 the payment basis determined under such competi-
23 tive acquisition program; and

24 “(ii) the Secretary may use information on the
25 payment determined under such competitive acqui-
26 sition programs to adjust the payment amount oth-
27 erwise recognized under subparagraph (B)(ii) for
28 an area that is not a competitive acquisition area
29 under section 1847, and in the case of such adjust-
30 ment, paragraphs (8) and (9) of section 1842(b)
31 shall not be applied.”.

32 (c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Sec-
33 retary shall conduct a study to determine the extent to which
34 (if any) suppliers of covered items of durable medical equip-
35 ment that are subject to the competitive acquisition program
36 under section 1847 of the Social Security Act, as amended by
37 subsection (a), are soliciting physicians to prescribe certain



1 brands or modes of delivery of covered items based on profit-
2 ability.

3 **SEC. 303. REFORM OF PAYMENT FOR DRUGS AND**
4 **BIOLOGICALS UNDER THE MEDICARE PRO-**
5 **GRAM.**

6 (a) PAYMENT REFORM.—

7 (1) IN GENERAL.—Section 1842(o) (42 U.S.C.
8 1395u(o)) is amended to read as follows:

9 “(o) PAYMENT FOR DRUGS AND BIOLOGICALS.—

10 “(1) GENERAL RULE.—If a physician’s, supplier’s, or
11 any other person’s bill or request for payment for services
12 includes a charge for a drug or biological for which pay-
13 ment may be made under this part and the drug or biologi-
14 cal is not paid on a cost or prospective payment basis as
15 otherwise provided in this part, the amount payable for the
16 drug or biological shall be based on the following:

17 “(A) MULTI-SOURCE (GENERIC) DRUGS.—In the
18 case of a drug or biological that meets the require-
19 ments for a multi-source drug under subclauses (I) and
20 (II) of section 1927(k)(7)(A)(i), 105 percent of the vol-
21 ume-weighted median average acquisition price for any
22 drug or biological covered under the same medicare
23 HCPCS code.

24 “(B) SINGLE SOURCE (BRAND) DRUGS AND
25 BIOLOGICALS.—In the case of a drug or biological that
26 meets the requirements for a single source drug under
27 section 1927(k)(7)(A)(iv), 105 percent of the average
28 acquisition price for the drug or biological.

29 “(C) ACCESS EXCEPTION.—The Secretary may
30 modify the rate otherwise applicable in order to assure
31 access to necessary drugs and biologicals in the case of
32 sole community providers in rural and other areas
33 where the providers are not reasonably able to obtain
34 the drugs and biologicals at the payment rates other-
35 wise applicable. Such modification shall not result in a
36 change of more than 15 percent of the rate otherwise
37 applicable.



1 “(D) DATA-RELATED EXCEPTION.—If the Sec-
2 retary determines that there is insufficient data avail-
3 able with respect to compute an average acquisition
4 price for a drug or biological for a quarter or that, be-
5 cause of a significant change in price from quarter-to-
6 quarter, the available data on the average acquisition
7 price does not accurately reflect the actual, current ac-
8 quisition cost for the drug or biological, the Secretary
9 may substitute for the quarters involved an appropriate
10 payment for the drug or biological for such average ac-
11 quisition price.

12 “(E) APPLICATION OF NDC CODES.—If the Sec-
13 retary determines that it is appropriate to provide for
14 payment under this subsection using national drug code
15 (NDC) instead of HCPCS codes, in applying subpara-
16 graph (A) the reference to the same HCPCS code shall
17 be deemed a reference to the appropriate national drug
18 codes for those drugs or biologicals that are therapeuti-
19 cally and pharmaceutically equivalent and bioequivalent
20 (as defined for purposes of section 1927(k)(7)(A)).

21 “(2) DEFINITION OF AVERAGE ACQUISITION PRICE.—

22 “(A) IN GENERAL.—For purposes of this sub-
23 section, the term ‘average acquisition price’ means,
24 with respect to a drug or biological and with respect to
25 each dosage form and strength of the drug or biological
26 product (without regard to any special packaging, label-
27 ing, or identifiers on the dosage form or product or
28 package), the average of all final sales prices charged
29 by the manufacturer of the drug or biological product
30 in the United States, excluding sales exempt from in-
31 clusion in the calculation of best price under section
32 1927(c)(1)(C) (other than under clause (ii)(III) of such
33 section) and excluding sales subject to a rebate under
34 section 1927, as reported under paragraph (3).

35 “(B) NET PRICE.—Such average acquisition price
36 shall be calculated net of all of the following (as esti-
37 mated by the Secretary):



- 1 “(i) Volume discounts.
- 2 “(ii) Prompt pay discounts and cash dis-
- 3 counts.
- 4 “(iii) Charge-backs.
- 5 “(iv) Short-dated product discounts (for spoil-
- 6 age and other factors).
- 7 “(v) Free goods and services.
- 8 “(vi) Rebates.
- 9 “(vii) All other price concessions provided by
- 10 the drug manufacturer.

11 The Secretary may make subsequent adjustments in
12 such average acquisition price to take into account up-
13 dated information and differences between the price
14 previously estimated and the actual average acquisition
15 price.

16 “(C) WEIGHTING.—The average of all final sales
17 prices described in subparagraph (A) shall be deter-
18 mined by dividing—

19 “(i) the sum of all final prices charged by the
20 manufacturer (net of the adjustments made under
21 subparagraph (B)) for sales in the period involved
22 that are included in subparagraph (A) for the drug
23 or biological, by

24 “(ii) the total number of units of such sales in
25 the period.

26 “(D) DISTRIBUTION OF REPORTS.—The Secretary
27 shall promptly distribute applicable payment rates
28 under this subsection to carriers and fiscal inter-
29 mediaries and other contractors that make payment for
30 drugs and biologicals under this section in order to
31 apply a uniform reimbursement rate under this section.

32 “(3) PRICE REPORTING REQUIREMENT.—

33 “(A) IN GENERAL.—As a condition for payment
34 for any drug or biological of a manufacturer under this
35 subsection, the manufacturer of the drug or biological
36 shall—



1 “(i) report, on a quarterly basis, to the Sec-
2 retary (or the Secretary’s designee) the manufac-
3 turer’s average acquisition price and the informa-
4 tion required under subparagraph (C) for all drugs
5 and biologicals of the manufacturer by national
6 drug code (NDC);

7 “(ii) maintain such records (in written or elec-
8 tronic form) regarding such sales and prices for all
9 such drugs and biologicals as may be necessary to
10 audit the information so reported or required to be
11 reported; and

12 “(iii) provide the Secretary with access to such
13 records in order to permit the Secretary to audit
14 information so reported or required to be reported.

15 “(B) PENALTIES.—The provisions of section
16 1927(b)(3)(C) shall apply with respect to the reporting
17 of information under subparagraph (A) in the same
18 manner as it applies to the reporting of information
19 under section 1927(b)(3)(A), except that the reference
20 in clause (i) of such section to \$10,000 is deemed a ref-
21 erence to \$100,000 and any reference to a suspension
22 of an agreement is deemed a reference to a suspension
23 of payment for the drug or biological involved under
24 this part. The Secretary shall promptly refer to the In-
25 spector General of the Department of Health and
26 Human Services and, if appropriate, to appropriate of-
27 ficials in the Department of Justice cases in which the
28 Secretary becomes aware of a false price representation
29 made in the information submitted under this para-
30 graph.

31 “(C) FORM OF REPORTING.—Information required
32 to be reported under subparagraph (A)(i) shall be re-
33 ported in a form and manner specified by the Sec-
34 retary. The information required to be reported shall
35 include the identification of the generic name of the
36 drug or biological and its brand name (if any), the na-
37 tional drug code (NDC) and the HCPCS code assigned



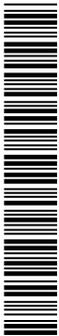
1 to the drug or biological, the dosage form, strength,
2 volume, and package size involved. The information for
3 a quarter shall be submitted not later than 30 days
4 after the end of the quarter. The information shall be
5 accompanied by a written and signed certification by
6 an officer of the manufacturer attesting to the accuracy
7 of the information reported. Such information shall in-
8 clude updated information on the net price realized
9 (taking into account rebates and other amounts affect-
10 ing net price), regardless of the period for which such
11 a rebate or other adjustment in net price might have
12 been earned.

13 “(D) AUDITING.—The Secretary shall audit on a
14 periodic basis information reported or required to be
15 reported under this paragraph. The Secretary may con-
16 duct such independent price gathering activities, such
17 as surveys and review of published catalog information
18 or other transactional information, as may be appro-
19 priate to verify the accuracy of the information re-
20 ported.

21 “(4) DISPENSING FEE.—If payment for a drug or bio-
22 logical is made to a licensed pharmacy approved to dispense
23 drugs or biologicals under this part, the Secretary shall pay
24 a dispensing fee (less the applicable deductible and coinsur-
25 ance amounts) to the pharmacy. Such a dispensing fee
26 shall be subject to adjustment from year to year based
27 upon changes in the consumer price index over time and
28 may be adjusted as the Secretary determines to be appro-
29 priate to reflect differences in the costs of dispensing dif-
30 ferent drugs and biologicals.

31 “(5) PAYMENT REQUIRED ON AN ASSIGNMENT-RE-
32 LATED BASIS.—

33 “(A) IN GENERAL.—Payment for a charge for any
34 drug or biological for which payment may be made
35 under this part may be made only on an assignment-
36 related basis.



1 “(B) APPLICATION OF ENFORCEMENT PROVI-
2 SIONS.—The provisions of subsection (b)(18)(B) shall
3 apply to charges for such drugs or biologicals in the
4 same manner as they apply to services furnished by a
5 practitioner described in subsection (b)(18)(C).”.

6 (2) EFFECTIVE DATE.—Subject to subsection (i)(2),
7 the amendment made by paragraph (1) shall apply to drugs
8 and biologicals furnished on or after January 1, 2004.

9 (b) MEDICARE PAYMENT FOR DRUG ADMINISTRATION
10 SERVICES.—

11 (1) IN GENERAL.—The Secretary shall revise the prac-
12 tice expense relative value units for drug administration
13 services for years beginning with the year 2005 in accord-
14 ance with this subsection. For purposes of this subsection,
15 the term “drug administration services” includes chemo-
16 therapy administration services, therapeutic and diagnostic
17 infusions and injections, and such other services as the Sec-
18 retary specifies.

19 (2) DIRECT COSTS EQUAL TO 100 PERCENT OF CPEP
20 ESTIMATES.—Using the information, including estimates of
21 clinical staff time, developed in the clinical practice expert
22 panel process, including refinements by American Medical
23 Association committees, the Secretary shall estimate the
24 costs of the nursing and other clinical staff, supplies, and
25 procedure-specific equipment (exceeding a cost specified by
26 the Secretary) used in furnishing each type of drug admin-
27 istration service. The Secretary shall utilize without revi-
28 sion the minutes of clinical staff time determined in such
29 process. The Secretary shall convert the information from
30 such process to estimated costs by applying the most cur-
31 rent available data on staff salary, supply, and equipment
32 costs, and such costs shall be updated to 2005 based on es-
33 timated changes in prices since the date of such data.

34 (3) TOTAL PRACTICE EXPENSES.—The Secretary shall
35 estimate the total practice expenses of each drug adminis-
36 tration service by assuming that the direct costs for the



1 service determined under paragraph (3) are 33.2 percent of
2 such total practice expenses.

3 (4) CONVERSION TO RELATIVE VALUE UNITS.—The
4 Secretary shall convert the total practice expenses deter-
5 mined under paragraph (3) to practice expense relative
6 value units for each drug administration service by dividing
7 such expenses by the conversion factor that will be in effect
8 for the physician fee schedule for 2005. The relative value
9 units as so determined shall be used in determining the fee
10 schedule amounts paid for drug administration services
11 under section 1848 of the Social Security Act (42 U.S.C.
12 1395w-4).

13 (5) UPDATES.—For years after 2005, the relative val-
14 ues determined under paragraph (4) shall continue in effect
15 except that the Secretary shall revise them as necessary to
16 maintain their accuracy, provided that such revisions are
17 consistent with the methodology set forth in this sub-
18 section.

19 (6) MULTIPLE PUSHES.—In establishing the payment
20 amounts under this subsection, the Secretary shall establish
21 the payment amount for intravenous chemotherapy admin-
22 istration by push technique based on the administration of
23 a single drug. The Secretary shall make the same payment
24 for each additional drug administered by push technique
25 during the same encounter, except to the extent that the
26 Secretary finds that the cost of administering additional
27 drugs is less than the cost of administering the first drug.

28 (c) PAYMENTS FOR CHEMOTHERAPY SUPPORT SERV-
29 ICES.—

30 (1) GENERAL.—Beginning in 2005, the Secretary
31 shall recognize and make payments under section 1848 of
32 the Social Security Act (42 U.S.C. 1395w-4) for chemo-
33 therapy support services furnished incident to physicians'
34 services. For the purposes of this section, the term "chemo-
35 therapy support services" are services furnished by the
36 staff of physicians to patients undergoing treatment for
37 cancer that were not included in the computation of clinical



1 staff costs under subsection b(2). Such services include so-
2 cial worker services, nutrition counseling, psychosocial serv-
3 ices, and similar services.

4 (2) DIRECT COSTS.—The Secretary shall estimate the
5 cost of the salary and benefits of staff furnishing chemo-
6 therapy support services as they are provided in oncology
7 practices that furnish these services to cancer patients in
8 a manner that is considered to be high quality care. The
9 estimate shall be based on the weekly cost of such services
10 per patient receiving chemotherapy.

11 (3) TOTAL COSTS.—The Secretary shall estimate the
12 total practice expenses of chemotherapy support services by
13 assuming that the direct costs for the service determined
14 under paragraph (2) are 33.2 percent of such total practice
15 expenses.

16 (4) CONVERSION TO RELATIVE VALUE UNITS.—The
17 Secretary shall convert the total practice expenses deter-
18 mined under paragraph (3) to practice expense relative
19 value units for chemotherapy support services by dividing
20 such expenses by the conversion factor that will be in effect
21 for the physician fee schedule for 2005. The relative value
22 units as so determined shall be used in determining the fee
23 schedule amounts paid for chemotherapy support services
24 under such section 1848.

25 (5) UPDATES.—For years after 2005, the relative val-
26 ues determined under paragraph (4) shall continue in effect
27 except that the Secretary shall revise them as necessary to
28 maintain their accuracy, provided that such revisions are
29 consistent with the methodology set forth in this sub-
30 section.

31 (d) CANCER THERAPY MANAGEMENT SERVICES.—Begin-
32 ning in 2005, the Secretary shall recognize and establish a pay-
33 ment amount for the service of cancer therapy management to
34 account for the greater pre-service and post-service work asso-
35 ciated with visits and consultations conducted by physicians
36 treating cancer patients compared to typical visits and con-



1 sultations. The payment amount may vary by the level and type
2 of the related visit or consultation.

3 (e) OTHER SERVICES WITHOUT PHYSICIAN WORK REL-
4 ATIVE VALUE UNITS.—Beginning in 2005, the Secretary shall
5 develop a revised methodology for determining the payment
6 amounts for services that are paid under the fee schedule es-
7 tablished by section 1848 of the Social Security Act (42 U.S.C.
8 1395w-4) and that do not have physician work relative value
9 units, including radiation oncology services. Such methodology
10 shall result in payment amounts that fully cover the costs of
11 furnishing such services. Until such time as the methodology
12 for such services is revised and implemented, all such services
13 shall be protected from further payment cuts due to factors
14 such as shifts in utilization or removal of any one specialty's
15 services that are paid under the fee schedule established by
16 such section 1848 and that do not have physician work relative
17 value units.

18 (f) REPORT TO CONGRESS.—Not later than April 1, 2004,
19 the Secretary shall submit to Congress a report on the payment
20 amounts that are projected to be adopted under subsections
21 (b), (c), (d), and (e) of this section.

22 (g) INSTITUTE OF MEDICINE STUDY.—

23 (1) GENERAL.—The Secretary shall request the Insti-
24 tute of Medicine to conduct the study described in this sub-
25 section.

26 (2) BASELINE STUDY.—The first phase of the study
27 shall include the following objectives:

28 (A) An assessment of the extent to which the cur-
29 rent medicare payment system, prior to implementation
30 of the amendments made by this section, facilitates ap-
31 propriate access to care by cancer patients in the var-
32 ious treatment settings.

33 (B) The identification of the comprehensive range
34 of services furnished to cancer patients in the out-
35 patient setting, including support services such as psy-
36 chosocial services and counseling, and recommendations



1 regarding the types of services that ought to be fur-
2 nished to medicare patients with cancer.

3 (C) A discussion of the practice standards nec-
4 essary to assure the safe provision of services to cancer
5 patients.

6 (D) An analysis of the extent to which the current
7 medicare payment system supports the role of nurses
8 in the provision of oncology services and recommenda-
9 tions for any necessary improvements in the payment
10 system in that respect.

11 (E) The development of a framework for assessing
12 how the amendments made by this act affect the provi-
13 sion of care to medicare patients with cancer in the
14 various treatment settings.

15 (3) SECOND PHASE OF STUDY.—After the implemen-
16 tation of the amendments made by this section, the study
17 shall determine whether and how those amendments af-
18 fected the provision of care to medicare patients with can-
19 cer.

20 (4) CONSULTATION.—The Institute of Medicine shall
21 consult with the National Cancer Policy Board and organi-
22 zations representing cancer patients and survivors,
23 oncologists, oncology nurses, social workers, cancer centers,
24 and other healthcare professionals who treat cancer pa-
25 tients in planning and carrying out this study.

26 (5) DUE DATES.—

27 (A) The study required by paragraph (2) shall be
28 submitted to the Congress and the Secretary of Health
29 and Human Services no later than June 30, 2004.

30 (B) The study required by paragraph (3) shall be
31 submitted to the Congress and the Secretary of Health
32 and Human Services no later than December 31, 2006.

33 (i) STUDY OF PAYMENTS FOR BLOOD CLOTTING FACTORS
34 AND OTHER BIOLOGICALS.—

35 (1) IN GENERAL.—The Secretary of Health and
36 Human Services shall provide for a study of the appro-
37 priateness of the medicare payment methodology for blood



1 clotting factors and other biologicals under part B of title
2 XVIII of the Social Security Act. Not later than 9 months
3 after the date of the enactment of this Act, the Secretary
4 shall submit to Congress a report on such study and shall
5 include in such report recommendations regarding whether
6 to apply the payment methodology provided under the
7 amendment made by subsection (a)(1) and alternative rec-
8 ommendations for appropriate dispensing fees.

9 (2) DELAY IN EFFECTIVE DATE.—The amendment
10 made by subsection (a)(1) shall not apply to blood clotting
11 factors furnished before the first day of the first calendar
12 year that begins at least 6 months after the date the report
13 under paragraph (1) has been submitted to the Congress.

14 **SEC. 304. DEMONSTRATION PROJECT FOR USE OF RE-**
15 **COVERY AUDIT CONTRACTORS.**

16 (a) IN GENERAL.—The Secretary of Health and Human
17 Services shall conduct a demonstration project under this sec-
18 tion (in this section referred to as the “project”) to dem-
19 onstrate the use of recovery audit contractors under the Medi-
20 care Integrity Program in identifying underpayments and over-
21 payments and recouping overpayments under the medicare pro-
22 gram for services for which payment is made under part A or
23 part B of title XVIII of the Social Security Act. Under the
24 project—

25 (1) payment may be made to such a contractor on a
26 contingent basis;

27 (2) a percentage of the amount recovered may be re-
28 tained by the Secretary and shall be available to the pro-
29 gram management account of the Centers for Medicare &
30 Medicaid Services; and

31 (3) the Secretary shall examine the efficacy of such
32 use with respect to duplicative payments, accuracy of cod-
33 ing, and other payment policies in which inaccurate pay-
34 ments arise.

35 (b) SCOPE AND DURATION.—

36 (1) SCOPE.—The project shall cover at least 2 States
37 that are among the States with—



1 (A) the highest per capita utilization rates of
2 medicare services, and

3 (B) at least 3 contractors.

4 (2) DURATION.—The project shall last for not longer
5 than 3 years.

6 (c) WAIVER.—The Secretary of Health and Human Serv-
7 ices shall waive such provisions of title XVIII of the Social Se-
8 curity Act as may be necessary to provide for payment for serv-
9 ices under the project in accordance with subsection (a).

10 (d) QUALIFICATIONS OF CONTRACTORS.—

11 (1) IN GENERAL.—The Secretary shall enter into a re-
12 covery audit contract under this section with an entity only
13 if the entity has staff that has the appropriate clinical
14 knowledge of and experience with the payment rules and
15 regulations under the medicare program or the entity has
16 or will contract with another entity that has such knowl-
17 edgeable and experienced staff.

18 (2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The
19 Secretary may not enter into a recovery audit contract
20 under this section with an entity to the extent that the en-
21 tity is a fiscal intermediary under section 1816 of the So-
22 cial Security Act (42 U.S.C. 1395h), a carrier under sec-
23 tion 1842 of such Act (42 U.S.C. 1395u), or a Medicare
24 Administrative Contractor under section 1874A of such
25 Act.

26 (3) PREFERENCE FOR ENTITIES WITH DEM-
27 ONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In
28 awarding contracts to recovery audit contractors under this
29 section, the Secretary shall give preference to those risk en-
30 tities that the Secretary determines have demonstrated
31 more than 3 years direct management experience and a
32 proficiency in recovery audits with private insurers or
33 under the medicaid program under title XIX of such Act.

34 (e) CONSTRUCTION RELATING TO CONDUCT OF INVES-
35 TIGATION OF FRAUD.—A recovery of an overpayment to a pro-
36 vider by a recovery audit contractor shall not be construed to
37 prohibit the Secretary or the Attorney General from inves-



1 tigating and prosecuting, if appropriate, allegations of fraud or
2 abuse arising from such overpayment.

3 (f) REPORT.—The Secretary of Health and Human Serv-
4 ices shall submit to Congress a report on the project not later
5 than 6 months after the date of its completion. Such reports
6 shall include information on the impact of the project on sav-
7 ings to the medicare program and recommendations on the
8 cost-effectiveness of extending or expanding the project.

9 **TITLE IV—RURAL HEALTH CARE**
10 **IMPROVEMENTS**

11 **SEC. 401. FAIRNESS IN THE MEDICARE DISPROPOR-**
12 **TIONATE SHARE HOSPITAL (DSH) ADJUST-**
13 **MENT FOR RURAL HOSPITALS.**

14 (a) EQUALIZING DSH PAYMENT AMOUNTS.—

15 (1) IN GENERAL.—Section 1886(d)(5)(F)(vii) (42
16 U.S.C. 1395ww(d)(5)(F)(vii)) is amended by inserting “,
17 and, after October 1, 2004, for any other hospital described
18 in clause (iv),” after “clause (iv)(I)” in the matter pre-
19 ceding subclause (I).

20 (2) CONFORMING AMENDMENTS.—Section
21 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

22 (A) in clause (iv)—

23 (i) in subclause (II)—

24 (I) by inserting “and before October 1,
25 2004,” after “April 1, 2001,”; and

26 (II) by inserting “or, for discharges occur-
27 ring on or after October 1, 2004, is equal to
28 the percent determined in accordance with the
29 applicable formula described in clause (vii)”
30 after “clause (xiii)”;

31 (ii) in subclause (III)—

32 (I) by inserting “and before October 1,
33 2004,” after “April 1, 2001,”; and

34 (II) by inserting “or, for discharges occur-
35 ring on or after October 1, 2004, is equal to
36 the percent determined in accordance with the



1 applicable formula described in clause (vii)”
2 after “clause (xii)”;

3 (iii) in subclause (IV)—

4 (I) by inserting “and before October 1,
5 2004,” after “April 1, 2001,”; and

6 (II) by inserting “or, for discharges occur-
7 ring on or after October 1, 2004, is equal to
8 the percent determined in accordance with the
9 applicable formula described in clause (vii)”
10 after “clause (x) or (xi)”;

11 (iv) in subclause (V)—

12 (I) by inserting “and before October 1,
13 2004,” after “April 1, 2001,”; and

14 (II) by inserting “or, for discharges occur-
15 ring on or after October 1, 2004, is equal to
16 the percent determined in accordance with the
17 applicable formula described in clause (vii)”
18 after “clause (xi)”;

19 (v) in subclause (VI)—

20 (I) by inserting “and before October 1,
21 2004,” after “April 1, 2001,”; and

22 (II) by inserting “or, for discharges occur-
23 ring on or after October 1, 2004, is equal to
24 the percent determined in accordance with the
25 applicable formula described in clause (vii)”
26 after “clause (x)”;

27 (B) in clause (viii), by striking “The formula” and
28 inserting “For discharges occurring before October 1,
29 2004, the formula”;

30 (C) in each of clauses (x), (xi), (xii), and (xiii), by
31 striking “For purposes” and inserting “With respect to
32 discharges occurring before October 1, 2004, for pur-
33 poses”.

34 (b) EFFECTIVE DATE.—The amendments made by this
35 section shall apply to discharges occurring on or after October
36 1, 2004.



1 **SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM**
2 **STANDARDIZED AMOUNT IN RURAL AND**
3 **SMALL URBAN AREAS.**

4 (a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C.
5 1395ww(d)(3)(A)) is amended—

6 (1) in clause (iv), by inserting “and ending on or be-
7 fore September 30, 2003,” after “October 1, 1995,”; and

8 (2) by redesignating clauses (v) and (vi) as clauses
9 (vii) and (viii), respectively, and inserting after clause (iv)
10 the following new clauses:

11 “(v) For discharges occurring in the fiscal year begin-
12 ning on October 1, 2003, the average standardized amount
13 for hospitals located in areas other than a large urban area
14 shall be equal to the average standardized amount for hos-
15 pitals located in a large urban area.”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) COMPUTING DRG-SPECIFIC RATES.—Section
18 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

19 (A) in the heading, by striking “IN DIFFERENT
20 AREAS”;

21 (B) in the matter preceding clause (i), by striking
22 “, each of”;

23 (C) in clause (i)—

24 (i) in the matter preceding subclause (I), by
25 inserting “for fiscal years before fiscal year 2004,”
26 before “for hospitals”; and

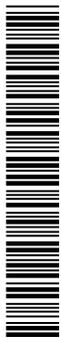
27 (ii) in subclause (II), by striking “and” after
28 the semicolon at the end;

29 (D) in clause (ii)—

30 (i) in the matter preceding subclause (I), by
31 inserting “for fiscal years before fiscal year 2004,”
32 before “for hospitals”; and

33 (ii) in subclause (II), by striking the period at
34 the end and inserting “; and”; and

35 (E) by adding at the end the following new clause:



1 “(iii) for a fiscal year beginning after fiscal year
2 2003, for hospitals located in all areas, to the product
3 of—

4 “(I) the applicable standardized amount (com-
5 puted under subparagraph (A)), reduced under
6 subparagraph (B), and adjusted or reduced under
7 subparagraph (C) for the fiscal year; and

8 “(II) the weighting factor (determined under
9 paragraph (4)(B)) for that diagnosis-related
10 group.”.

11 (2) TECHNICAL CONFORMING SUNSET.—Section
12 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

13 (A) in the matter preceding subparagraph (A), by
14 inserting “, for fiscal years before fiscal year 1997,”
15 before “a regional adjusted DRG prospective payment
16 rate”; and

17 (B) in subparagraph (D), in the matter preceding
18 clause (i), by inserting “, for fiscal years before fiscal
19 year 1997,” before “a regional DRG prospective pay-
20 ment rate for each region,”.

21 **SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOS-**
22 **PITAL CLASSIFICATION.**

23 (a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C.
24 1395x(mm)) is amended—

25 (1) in the heading by adding “ESSENTIAL RURAL
26 HOSPITALS” at the end; and

27 (2) by adding at the end the following new para-
28 graphs:

29 “(4)(A) The term ‘essential rural hospital’ means a sub-
30 section (d) hospital (as defined in section 1886(d)(1)(B)) that
31 is located in a rural area (as defined for purposes of section
32 1886(d)), has more than 25 licensed acute care inpatient beds,
33 has applied to the Secretary for classification as such a hos-
34 pital, and with respect to which the Secretary has determined
35 that the closure of the hospital would significantly diminish the
36 ability of medicare beneficiaries to obtain essential health care
37 services.



1 “(B) The determination under subparagraph (A) shall be
2 based on the following criteria:

3 “(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES
4 RECEIVING CARE FROM HOSPITAL.—(I) A high percentage
5 of such beneficiaries residing in the area of the hospital
6 who are hospitalized (during the most recent year for which
7 complete data are available) receive basic inpatient medical
8 care at the hospital.

9 “(II) For a hospital with more than 200 licensed beds,
10 a high percentage of such beneficiaries residing in such
11 area who are hospitalized (during such recent year) receive
12 specialized surgical inpatient care at the hospital.

13 “(III) Almost all physicians described in section
14 1861(r)(1) in such area have privileges at the hospital and
15 provide their inpatient services primarily at the hospital.

16 “(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF
17 HOSPITAL.—If the hospital were to close—

18 “(I) there would be a significant amount of time
19 needed for residents to reach emergency treatment, re-
20 sulting in a potential significant harm to beneficiaries
21 with critical illnesses or injuries;

22 “(II) there would be an inability in the community
23 to stabilize emergency cases for transfers to another
24 acute care setting, resulting in a potential for signifi-
25 cant harm to medicare beneficiaries; and

26 “(III) any other nearby hospital lacks the physical
27 and clinical capacity to take over the hospital’s typical
28 admissions.

29 “(C) In making such determination, the Secretary may
30 also consider the following:

31 “(i) Free-standing ambulatory surgery centers, office-
32 based oncology care, and imaging center services are insuf-
33 ficient in the hospital’s area to handle the outpatient care
34 of the hospital.

35 “(ii) Beneficiaries in nearby areas would be adversely
36 affected if the hospital were to close as the hospital pro-



1 provides specialized knowledge and services to a network of
2 smaller hospitals and critical access hospitals.

3 “(iii) Medicare beneficiaries would have difficulty in
4 accessing care if the hospital were to close as the hospital
5 provides significant subsidies to support ambulatory care in
6 local clinics, including mental health clinics and to support
7 post acute care.

8 “(iv) The hospital has a committment to provide grad-
9 uate medical education in a rural area.

10 “(C) QUALITY CARE.—The hospital inpatient score for
11 quality of care is not less than the median hospital score
12 for qualify of care for hospitals in the State, as established
13 under standards of the utilization and quality control peer
14 review organization under part B of title XI or other qual-
15 ity standards recognized by the Secretary.

16 A hospital classified as an essential rural hospital may not
17 change such classification and a hospital so classified shall not
18 be treated as a sole community hospital, medicare dependent
19 hospital, or rural referral center for purposes of section 1886.”.

20 (b) PAYMENT BASED ON 102 PERCENT OF ALLOWED
21 COSTS.—

22 (1) INPATIENT HOSPITAL SERVICES.—Section 1886(d)
23 (42 U.S.C. 1395ww(d)) is amended by adding at the end
24 the following:

25 “(11) In the case of a hospital classified as an essential
26 rural hospital under section 1861(mm)(4) for a cost reporting
27 period, the payment under this subsection for inpatient hospital
28 services for discharges occurring during the period shall be
29 based on 102 percent of the reasonable costs for such services.
30 Nothing in this paragraph shall be construed as affecting the
31 application or amount of deductibles or copayments otherwise
32 applicable to such services under part A or as waiving any re-
33 quirement for billing for such services.”.

34 (2) HOSPITAL OUTPATIENT SERVICES.—Section
35 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by add-
36 ing at the end the following new subparagraph:



1 “(B) SPECIAL RULE FOR ESSENTIAL RURAL HOS-
2 PITALS.—In the case of a hospital classified as an es-
3 sential rural hospital under section 1861(mm)(4) for a
4 cost reporting period, the payment under this sub-
5 section for covered OPD services during the period
6 shall be based on 102 percent of the reasonable costs
7 for such services. Nothing in this subparagraph shall be
8 construed as affecting the application or amount of
9 deductibles or copayments otherwise applicable to such
10 services under this part or as waiving any requirement
11 for billing for such services.”.

12 (c) EFFECTIVE DATE.—The amendments made by this
13 section shall apply to cost reporting periods beginning on or
14 after October 1, 2004.

15 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED**
16 **IN HOSPITAL MARKET BASKET.**

17 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-
18 vising the weights used in the hospital market basket under
19 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.
20 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-
21 able, the Secretary shall establish a frequency for revising such
22 weights, including the labor share, in such market basket to re-
23 flect the most current data available more frequently than once
24 every 5 years.

25 (b) REPORT.—Not later than October 1, 2004, the Sec-
26 retary shall submit a report to Congress on the frequency es-
27 tablished under subsection (a), including an explanation of the
28 reasons for, and options considered, in determining such fre-
29 quency.

30 **SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOS-**
31 **PITAL PROGRAM.**

32 (a) INCREASE IN PAYMENT AMOUNTS.—

33 (1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and
34 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C.
35 1395tt(a)(3)) are each amended by inserting “equal to 102
36 percent of” before “the reasonable costs”.



1 (2) EFFECTIVE DATE.—The amendments made by
2 paragraph (1) shall apply to payments for services fur-
3 nished during cost reporting periods beginning on or after
4 October 1, 2003.

5 (b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY
6 ROOM ON-CALL PROVIDERS.—

7 (1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C.
8 1395m(g)(5)) is amended—

9 (A) in the heading—

10 (i) by inserting “CERTAIN” before “EMER-
11 GENCY”; and

12 (ii) by striking “PHYSICIANS” and inserting
13 “PROVIDERS”;

14 (B) by striking “emergency room physicians who
15 are on-call (as defined by the Secretary)” and inserting
16 “physicians, physician assistants, nurse practitioners,
17 and clinical nurse specialists who are on-call (as de-
18 fined by the Secretary) to provide emergency services”;
19 and

20 (C) by striking “physicians’ services” and insert-
21 ing “services covered under this title”.

22 (2) EFFECTIVE DATE.—The amendment made by
23 paragraph (1) shall apply with respect to costs incurred for
24 services provided on or after January 1, 2004.

25 (c) PERMITTING CAHS TO ALLOCATE SWING BEDS AND
26 ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL LIMIT
27 OF 25 BEDS.—

28 (1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42
29 U.S.C. 1395i-4(c)(2)(B)(iii)) is amended to read as fol-
30 lows:

31 “(iii) provides not more than a total of 25 ex-
32 tended care service beds (pursuant to an agreement
33 under subsection (f)) and acute care inpatient beds
34 (meeting such standards as the Secretary may es-
35 tablish) for providing inpatient care for a period
36 that does not exceed, as determined on an annual,
37 average basis, 96 hours per patient;”.



1 (2) CONFORMING AMENDMENT.—Section 1820(f) (42
2 U.S.C. 1395i-4(f)) is amended by striking “and the num-
3 ber of beds used at any time for acute care inpatient serv-
4 ices does not exceed 15 beds”.

5 (3) EFFECTIVE DATE.—The amendments made by
6 this subsection shall with respect to designations made on
7 or after October 1, 2004.

8 (d) ELIMINATION OF THE ISOLATION TEST FOR COST-
9 BASED CAH AMBULANCE SERVICES.—

10 (1) ELIMINATION.—

11 (A) IN GENERAL.—Section 1834(l)(8) (42 U.S.C.
12 1395m(l)(8)), as added by section 205(a) of BIPA
13 (114 Stat. 2763A-482), is amended by striking the
14 comma at the end of subparagraph (B) and all that fol-
15 lows and inserting a period.

16 (B) EFFECTIVE DATE.—The amendment made by
17 subparagraph (A) shall apply to services furnished on
18 or after January 1, 2005.

19 (2) TECHNICAL CORRECTION.—Section 1834(l) (42
20 U.S.C. 1395m(l)) is amended by redesignating paragraph
21 (8), as added by section 221(a) of BIPA (114 Stat.
22 2763A-486), as paragraph (9).

23 (e) REINSTATEMENT OF PERIODIC INTERIM PAYMENT
24 (PIP).—

25 (1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C.
26 1395g(e)(2)) is amended—

27 (A) in the matter before subparagraph (A), by in-
28 serting “, in the cases described in subparagraphs (A)
29 through (D)” after “1986”; and

30 (B) by striking “and” at the end of subparagraph
31 (C);

32 (C) by adding “and” at the end of subparagraph
33 (D); and

34 (D) by inserting after subparagraph (D) the fol-
35 lowing new subparagraph:

36 “(E) inpatient critical access hospital services;”.



1 (2) DEVELOPMENT OF ALTERNATIVE METHODS OF
2 PERIODIC INTERIM PAYMENTS.—With respect to periodic
3 interim payments to critical access hospitals for inpatient
4 critical access hospital services under section 1815(e)(2)(E)
5 of the Social Security Act, as added by paragraph (1), the
6 Secretary shall develop alternative methods for such pay-
7 ments that are based on expenditures of the hospital.

8 (3) REINSTATEMENT OF PIP.—The amendments made
9 by paragraph (1) shall apply to payments made on or after
10 January 1, 2004.

11 (f) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN
12 PAYMENT ADJUSTMENT.—

13 (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C.
14 1395m(g)(2)) is amended by adding after and below sub-
15 paragraph (B) the following:

16 “The Secretary may not require, as a condition for apply-
17 ing subparagraph (B) with respect to a critical access hos-
18 pital, that each physician providing professional services in
19 the hospital must assign billing rights with respect to such
20 services, except that such subparagraph shall not apply to
21 those physicians who have not assigned such billing
22 rights.”.

23 (2) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall be effective as if included in the enact-
25 ment of section 403(d) of the Medicare, Medicaid, and
26 SCHIP Balanced Budget Refinement Act of 1999 (113
27 Stat. 1501A–371).

28 (g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR
29 GRANT PROGRAM.—

30 (1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i-
31 4(g)) is amended by adding at the end the following new
32 paragraph:

33 “(4) FUNDING.—

34 “(A) IN GENERAL.—Subject to subparagraph (B),
35 payment for grants made under this subsection during
36 fiscal years 2004 through 2008 shall be made from the
37 Federal Hospital Insurance Trust Fund.



1 “(B) ANNUAL AGGREGATE LIMITATION.—In no
2 case may the amount of payment provided for under
3 subparagraph (A) for a fiscal year exceed
4 \$25,000,000.”.

5 (2) CONFORMING AMENDMENT.—Section 1820 (42
6 U.S.C. 1395i-4) is amended by striking subsection (j).

7 **SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
8 **TIONS.**

9 (a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C.
10 1395ww(h)(4)) is amended—

11 (1) in subparagraph (F)(i), by inserting “subject to
12 subparagraph (I),” after “October 1, 1997,”;

13 (2) in subparagraph (H)(i), by inserting “subject to
14 subparagraph (I),” after “subparagraphs (F) and (G),”;
15 and

16 (3) by adding at the end the following new subpara-
17 graph:

18 “(I) REDISTRIBUTION OF UNUSED RESIDENT PO-
19 SITIONS.—

20 “(i) REDUCTION IN LIMIT BASED ON UNUSED
21 POSITIONS.—

22 “(I) IN GENERAL.—If a hospital’s resident
23 level (as defined in clause (iii)(I)) is less than
24 the otherwise applicable resident limit (as de-
25 fined in clause (iii)(II)) for each of the ref-
26 erence periods (as defined in subclause (II)),
27 effective for cost reporting periods beginning on
28 or after January 1, 2004, the otherwise appli-
29 cable resident limit shall be reduced by 75 per-
30 cent of the difference between such limit and
31 the reference resident level specified in sub-
32 clause (III) (or subclause (IV) if applicable).

33 “(II) REFERENCE PERIODS DEFINED.—In
34 this clause, the term ‘reference periods’ means,
35 for a hospital, the 3 most recent consecutive
36 cost reporting periods of the hospital for which



1 cost reports have been settled (or, if not, sub-
2 mitted) on or before September 30, 2002.

3 “(III) REFERENCE RESIDENT LEVEL.—
4 Subject to subclause (IV), the reference resi-
5 dent level specified in this subclause for a hos-
6 pital is the highest resident level for the hos-
7 pital during any of the reference periods.

8 “(IV) ADJUSTMENT PROCESS.—Upon the
9 timely request of a hospital, the Secretary may
10 adjust the reference resident level for a hospital
11 to be the resident level for the hospital for the
12 cost reporting period that includes July 1,
13 2003.

14 “(V) AFFILIATION.—With respect to hos-
15 pitals which are members of the same affiliated
16 group (as defined by the Secretary under sub-
17 paragraph (H)(ii)), the provisions of this sec-
18 tion shall be applied with respect to such an af-
19 filiated group by deeming the affiliated group
20 to be a single hospital.

21 “(ii) REDISTRIBUTION.—

22 “(I) IN GENERAL.—The Secretary is au-
23 thorized to increase the otherwise applicable
24 resident limits for hospitals by an aggregate
25 number estimated by the Secretary that does
26 not exceed the aggregate reduction in such lim-
27 its attributable to clause (i) (without taking
28 into account any adjustment under subclause
29 (IV) of such clause).

30 “(II) EFFECTIVE DATE.—No increase
31 under subclause (I) shall be permitted or taken
32 into account for a hospital for any portion of
33 a cost reporting period that occurs before July
34 1, 2004, or before the date of the hospital’s ap-
35 plication for an increase under this clause. No
36 such increase shall be permitted for a hospital



1 unless the hospital has applied to the Secretary
2 for such increase by December 31, 2005.

3 “(III) CONSIDERATIONS IN REDISTRIBU-
4 TION.—In determining for which hospitals the
5 increase in the otherwise applicable resident
6 limit is provided under subclause (I), the Sec-
7 retary shall take into account the need for such
8 an increase by specialty and location involved,
9 consistent with subclause (IV).

10 “(IV) PRIORITY FOR RURAL AND SMALL
11 URBAN AREAS.—In determining for which hos-
12 pitals and residency training programs an in-
13 crease in the otherwise applicable resident limit
14 is provided under subclause (I), the Secretary
15 shall first distribute the increase to programs
16 of hospitals located in rural areas or in urban
17 areas that are not large urban areas (as de-
18 fined for purposes of subsection (d)) on a first-
19 come-first-served basis (as determined by the
20 Secretary) based on a demonstration that the
21 hospital will fill the positions made available
22 under this clause and not to exceed an increase
23 of 25 full-time equivalent positions with respect
24 to any hospital.

25 “(V) APPLICATION OF LOCALITY AD-
26 JUSTED NATIONAL AVERAGE PER RESIDENT
27 AMOUNT.—With respect to additional residency
28 positions in a hospital attributable to the in-
29 crease provided under this clause, notwith-
30 standing any other provision of this subsection,
31 the approved FTE resident amount is deemed
32 to be equal to the locality adjusted national av-
33 erage per resident amount computed under
34 subparagraph (E) for that hospital.

35 “(VI) CONSTRUCTION.—Nothing in this
36 clause shall be construed as permitting the re-
37 distribution of reductions in residency positions



1 attributable to voluntary reduction programs
2 under paragraph (6) or as affecting the ability
3 of a hospital to establish new medical residency
4 training programs under subparagraph (H).

5 “(iii) RESIDENT LEVEL AND LIMIT DE-
6 FINED.—In this subparagraph:

7 “(I) RESIDENT LEVEL.—The term ‘resi-
8 dent level’ means, with respect to a hospital,
9 the total number of full-time equivalent resi-
10 dents, before the application of weighting fac-
11 tors (as determined under this paragraph), in
12 the fields of allopathic and osteopathic medi-
13 cine for the hospital.

14 “(II) OTHERWISE APPLICABLE RESIDENT
15 LIMIT.—The term ‘otherwise applicable resi-
16 dent limit’ means, with respect to a hospital,
17 the limit otherwise applicable under subpara-
18 graphs (F)(i) and (H) on the resident level for
19 the hospital determined without regard to this
20 subparagraph.”.

21 (b) CONFORMING AMENDMENT TO IME.—Section
22 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended
23 by adding at the end the following: “The provisions of subpara-
24 graph (I) of subsection (h)(4) shall apply with respect to the
25 first sentence of this clause in the same manner as it applies
26 with respect to subparagraph (F) of such subsection.”.

27 (c) REPORT ON EXTENSION OF APPLICATIONS UNDER
28 REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the
29 Secretary shall submit to Congress a report containing rec-
30 ommendations regarding whether to extend the deadline for ap-
31 plications for an increase in resident limits under section
32 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by
33 subsection (a)).



1 **SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS**
2 **PROVISIONS FOR SMALL RURAL HOSPITALS**
3 **AND SOLE COMMUNITY HOSPITALS UNDER**
4 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
5 **PITAL OUTPATIENT DEPARTMENT SERV-**
6 **ICES.**

7 (a) HOLD HARMLESS PROVISIONS.—

8 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42
9 U.S.C. 1395l(t)(7)(D)(i)) is amended—

10 (A) in the heading, by striking “SMALL” and in-
11 sserting “CERTAIN”;

12 (B) by inserting “or a sole community hospital (as
13 defined in section 1886(d)(5)(D)(iii)) located in a rural
14 area” after “100 beds”; and

15 (C) by striking “2004” and inserting “2006”.

16 (2) EFFECTIVE DATE.—The amendment made by sub-
17 section (a)(2) shall apply with respect to payment for OPD
18 services furnished on and after January 1, 2004.

19 (b) STUDY; ADJUSTMENT.—

20 (1) STUDY.—The Secretary shall conduct a study to
21 determine if, under the prospective payment system for
22 hospital outpatient department services under section
23 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)),
24 costs incurred by rural providers of services by ambulatory
25 payment classification groups (APCs) exceed those costs in-
26 curred by urban providers of services.

27 (2) ADJUSTMENT.—Insofar as the Secretary deter-
28 mines under paragraph (1) that costs incurred by rural
29 providers exceed those costs incurred by urban providers of
30 services, the Secretary shall provide for an appropriate ad-
31 justment under such section 1833(t) to reflect those higher
32 costs by January 1, 2005.

33 **SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLIN-**
34 **IC AND FEDERALLY QUALIFIED HEALTH**
35 **CENTER SERVICES FROM THE PROSPECTIVE**
36 **PAYMENT SYSTEM FOR SKILLED NURSING**
37 **FACILITIES.**

38 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.
39 1395yy(e)(2)(A)) is amended—



1 (1) in clause (i)(II), by striking “clauses (ii) and (iii)”
2 and inserting “clauses (ii), (iii), and (iv)”;

3 (2) by adding at the end the following new clause:

4 “(iv) EXCLUSION OF CERTAIN RURAL HEALTH
5 CLINIC AND FEDERALLY QUALIFIED HEALTH CEN-
6 TER SERVICES.—Services described in this clause
7 are—

8 “(I) rural health clinic services (as defined
9 in paragraph (1) of section 1861(aa)); and

10 “(II) Federally qualified health center
11 services (as defined in paragraph (3) of such
12 section);

13 that would be described in clause (ii) if such serv-
14 ices were not furnished by an individual affiliated
15 with a rural health clinic or a Federally qualified
16 health center.”.

17 (b) EFFECTIVE DATE.—The amendments made by sub-
18 section (a) shall apply to services furnished on or after January
19 1, 2004.

20 **SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTI-**
21 **TIONERS AS ATTENDING PHYSICIANS TO**
22 **SERVE HOSPICE PATIENTS.**

23 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C.
24 1395x(dd)(3)(B)) is amended by inserting “or nurse practi-
25 tioner (as defined in subsection (aa)(5))” after “the physician
26 (as defined in subsection (r)(1))”.

27 (b) PROHIBITION ON NURSE PRACTITIONER CERTIFYING
28 NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.
29 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for pur-
30 poses of this subparagraph does not include a nurse practi-
31 tioner)” after “attending physician (as defined in section
32 1861(dd)(3)(B))”.

33 **SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN**
34 **EMERGENCY CAPACITY FOR AMBULANCE**
35 **SERVICES IN RURAL AREAS.**

36 Section 1834(l) (42 U.S.C. 1395m(l)) is amended—



1 (1) by redesignating paragraph (8), as added by sec-
2 tion 221(a) of BIPA (114 Stat. 2763A-486), as paragraph
3 (9); and

4 (2) by adding at the end the following new paragraph:

5 “(10) ASSISTANCE FOR RURAL PROVIDERS FUR-
6 NISHING SERVICES IN LOW MEDICARE POPULATION DEN-
7 SITY AREAS.—

8 “(A) IN GENERAL.—In the case of ground ambu-
9 lance services furnished on or after January 1, 2004,
10 for which the transportation originates in a qualified
11 rural area (as defined in subparagraph (B)), the Sec-
12 retary shall provide for an increase in the base rate of
13 the fee schedule for mileage for a trip established under
14 this subsection. In establishing such increase, the Sec-
15 retary shall, based on the relationship of cost and vol-
16 ume, estimate the average increase in cost per trip for
17 such services as compared with the cost per trip for the
18 average ambulance service.

19 “(B) QUALIFIED RURAL AREA DEFINED.—For
20 purposes of subparagraph (A), the term ‘qualified rural
21 area’ is a rural area (as defined in section
22 1886(d)(2)(D)) with a population density of medicare
23 beneficiaries residing in the area that is in the lowest
24 three quartiles of all rural county populations.”.

25 **SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH**
26 **SERVICES FURNISHED IN A RURAL AREA.**

27 (a) IN GENERAL.—In the case of home health services fur-
28 nished in a rural area (as defined in section 1886(d)(2)(D) of
29 the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during
30 2004 and 2005, the Secretary shall increase the payment
31 amount otherwise made under section 1895 of such Act (42
32 U.S.C. 1395fff) for such services by 10 percent.

33 (b) WAIVING BUDGET NEUTRALITY.—The Secretary shall
34 not reduce the standard prospective payment amount (or
35 amounts) under section 1895 of the Social Security Act (42
36 U.S.C. 1395fff) applicable to home health services furnished



1 during a period to offset the increase in payments resulting
2 from the application of subsection (a).

3 **SEC. 412. PROVIDING SAFE HARBOR FOR CERTAIN COL-**
4 **LABORATIVE EFFORTS THAT BENEFIT MEDI-**
5 **CALLY UNDERSERVED POPULATIONS.**

6 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
7 1320a-7(b)(3)) is amended—

8 (1) in subparagraph (E), by striking “and” after the
9 semicolon at the end;

10 (2) in subparagraph (F), by striking the period at the
11 end and inserting “; and”; and

12 (3) by adding at the end the following new subpara-
13 graph:

14 “(G) any remuneration between a public or non-
15 profit private health center entity described under
16 clause (i) or (ii) of section 1905(l)(2)(B) and any indi-
17 vidual or entity providing goods, items, services, dona-
18 tions or loans, or a combination thereof, to such health
19 center entity pursuant to a contract, lease, grant, loan,
20 or other agreement, if such agreement contributes to
21 the ability of the health center entity to maintain or in-
22 crease the availability, or enhance the quality, of serv-
23 ices provided to a medically underserved population
24 served by the health center entity.”

25 (b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER
26 ENTITY ARRANGEMENTS.—

27 (1) ESTABLISHMENT.—

28 (A) IN GENERAL.—The Secretary of Health and
29 Human Services (in this subsection referred to as the
30 “Secretary”) shall establish, on an expedited basis,
31 standards relating to the exception described in section
32 1128B(b)(3)(G) of the Social Security Act, as added by
33 subsection (a), for health center entity arrangements to
34 the antikickback penalties.

35 (B) FACTORS TO CONSIDER.—The Secretary shall
36 consider the following factors, among others, in estab-



1 lishing standards relating to the exception for health
2 center entity arrangements under subparagraph (A):

3 (i) Whether the arrangement between the
4 health center entity and the other party results in
5 savings of Federal grant funds or increased reve-
6 nues to the health center entity.

7 (ii) Whether the arrangement between the
8 health center entity and the other party restricts or
9 limits a patient's freedom of choice.

10 (iii) Whether the arrangement between the
11 health center entity and the other party protects a
12 health care professional's independent medical
13 judgment regarding medically appropriate treat-
14 ment.

15 The Secretary may also include other standards and
16 criteria that are consistent with the intent of Congress
17 in enacting the exception established under this section.

18 (2) INTERIM FINAL EFFECT.—No later than 180 days
19 after the date of enactment of this Act, the Secretary shall
20 publish a rule in the Federal Register consistent with the
21 factors under paragraph (1)(B). Such rule shall be effective
22 and final immediately on an interim basis, subject to such
23 change and revision, after public notice and opportunity
24 (for a period of not more than 60 days) for public com-
25 ment, as is consistent with this subsection.

26 **SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
27 **PAYMENTS FOR PHYSICIANS' SERVICES.**

28 (a) STUDY.—The Comptroller General of the United
29 States shall conduct a study of differences in payment amounts
30 under the physician fee schedule under section 1848 of the So-
31 cial Security Act (42 U.S.C. 1395w-4) for physicians' services
32 in different geographic areas. Such study shall include—

33 (1) an assessment of the validity of the geographic ad-
34 justment factors used for each component of the fee sched-
35 ule;

36 (2) an evaluation of the measures used for such ad-
37 justment, including the frequency of revisions; and



1 (3) an evaluation of the methods used to determine
2 professional liability insurance costs used in computing the
3 malpractice component, including a review of increases in
4 professional liability insurance premiums and variation in
5 such increases by State and physician specialty and meth-
6 ods used to update the geographic cost of practice index
7 and relative weights for the malpractice component.

8 (b) REPORT.—Not later than 1 year after the date of the
9 enactment of this Act, the Comptroller General shall submit to
10 Congress a report on the study conducted under subsection (a).
11 The report shall include recommendations regarding the use of
12 more current data in computing geographic cost of practice in-
13 dices as well as the use of data directly representative of physi-
14 cians' costs (rather than proxy measures of such costs).

15 **SEC. 414. TREATMENT OF MISSING COST REPORTING**
16 **PERIODS FOR SOLE COMMUNITY HOS-**
17 **PITALS.**

18 (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.
19 1395ww(b)(3)(I)) is amended by adding at the end the fol-
20 lowing new clause:

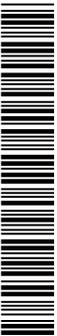
21 “(iii) In no case shall a hospital be denied treatment as
22 a sole community hospital or payment (on the basis of a target
23 rate as such as a hospital) because data are unavailable for any
24 cost reporting period due to changes in ownership, changes in
25 fiscal intermediaries, or other extraordinary circumstances, so
26 long as data for at least one applicable base cost reporting pe-
27 riod is available.”.

28 (b) EFFECTIVE DATE.—The amendment made by sub-
29 section (a) shall apply to cost reporting periods beginning on
30 or after January 1, 2004.

31 **SEC. 415. EXTENSION OF TELEMEDICINE DEMONSTRA-**
32 **TION PROJECT.**

33 Section 4207 of Balanced Budget Act of 1997 (Public
34 Law 105–33) is amended—

35 (1) in subsection (a)(4), by striking “4-year” and in-
36 serting “8-year”; and



1 (2) in subsection (d)(3), by striking “\$30,000,000”
2 and inserting “\$60,000,000”.

3 **SEC. 416. ADJUSTMENT TO THE MEDICARE INPATIENT**
4 **HOSPITAL PPS WAGE INDEX TO REVISE THE**
5 **LABOR-RELATED SHARE OF SUCH INDEX.**

6 (a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.
7 1395ww(d)(3)(E)) is amended—

8 (1) by striking “WAGE LEVELS.—The Secretary” and
9 inserting “WAGE LEVELS.—

10 “(i) IN GENERAL.—Except as provided in clause
11 (ii), the Secretary”; and

12 (2) by adding at the end the following new clause:

13 “(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED
14 BEGINNING IN FISCAL YEAR 2004.—

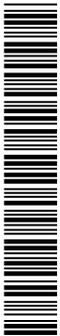
15 “(I) IN GENERAL.—Except as provided in sub-
16 clause (II), for discharges occurring on or after Oc-
17 tober 1, 2003, the Secretary shall substitute the
18 ‘62 percent’ for the proportion described in the
19 first sentence of clause (i).

20 “(II) HOLD HARMLESS FOR CERTAIN HOS-
21 PITALS.—If the application of subclause (I) would
22 result in lower payments to a hospital than would
23 otherwise be made, then this subparagraph shall be
24 applied as if this clause had not been enacted.”.

25 (b) WAIVING BUDGET NEUTRALITY.—Section
26 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by
27 subsection (a), is amended by adding at the end of clause (i)
28 the following new sentence: “The Secretary shall apply the pre-
29 vious sentence for any period as if the amendments made by
30 section 402(a) of the Medicare Prescription Drug and Mod-
31 ernization Act of 2003 had not been enacted.”.

32 **SEC. 417. MEDICARE INCENTIVE PAYMENT PROGRAM**
33 **IMPROVEMENTS FOR PHYSICIAN SCARCITY.**

34 (a) ADDITIONAL BONUS PAYMENT FOR CERTAIN PHYSI-
35 CIAN SCARCITY AREAS.—



1 (1) IN GENERAL.—Section 1833 (42 U.S.C. 1395l) is
2 amended by adding at the end the following new sub-
3 section:

4 “(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY
5 AREAS.—

6 “(1) IN GENERAL.—In the case of physicians’ services
7 furnished in a year—

8 “(A) by a primary care physician in a primary
9 care scarcity county (identified under paragraph (4));

10 or

11 “(B) by a physician who is not a primary care
12 physician in a specialist care scarcity county (as so
13 identified),

14 in addition to the amount of payment that would otherwise
15 be made for such services under this part, there also shall
16 be paid an amount equal to 5 percent of the payment
17 amount for the service under this part.

18 “(2) DETERMINATION OF RATIOS OF PHYSICIANS TO
19 MEDICARE BENEFICIARIES IN AREA.—Based upon available
20 data, the Secretary shall periodically determine, for each
21 county or equivalent area in the United States, the fol-
22 lowing:

23 “(A) NUMBER OF PHYSICIANS PRACTICING IN THE
24 AREA.—The number of physicians who furnish physi-
25 cians’ services in the active practice of medicine or os-
26 teopathy in that county or area, other than physicians
27 whose practice is exclusively for the Federal Govern-
28 ment, physicians who are retired, or physicians who
29 only provide administrative services. Of such number,
30 the number of such physicians who are—

31 “(i) primary care physicians; or

32 “(ii) physicians who are not primary care phy-
33 sicians.

34 “(B) NUMBER OF MEDICARE BENEFICIARIES RE-
35 SIDING IN THE AREA.—The number of individuals who
36 are residing in the county and are entitled to benefits
37 under part A or enrolled under this part, or both.



1 “(C) DETERMINATION OF RATIOS.—

2 “(i) PRIMARY CARE RATIO.—The ratio (in this
3 paragraph referred to as the ‘primary care ratio’)
4 of the number of primary care physicians (deter-
5 mined under subparagraph (A)(i)), to number of
6 medicare beneficiaries determined under subpara-
7 graph (B).

8 “(ii) SPECIALIST CARE RATIO.—The ratio (in
9 this paragraph referred to as the ‘specialist care
10 ratio’) of the number of other physicians (deter-
11 mined under subparagraph (A)(ii)), to number of
12 medicare beneficiaries determined under subpara-
13 graph (B).

14 “(3) RANKING OF COUNTIES.—The Secretary shall
15 rank each such county or area based separately on its pri-
16 mary care ratio and its specialist care ratio.

17 “(4) IDENTIFICATION OF COUNTIES.—The Secretary
18 shall identify—

19 “(A) those counties and areas (in this paragraph
20 referred to as ‘primary care scarcity counties’) with the
21 lowest primary care ratios that represent, if each such
22 county or area were weighted by the number of medi-
23 care beneficiaries determined under paragraph (2)(B),
24 an aggregate total of 20 percent of the total of the
25 medicare beneficiaries determined under such para-
26 graph; and

27 “(B) those counties and areas (in this subsection
28 referred to as ‘specialist care scarcity counties’) with
29 the lowest specialist care ratios that represent, if each
30 such county or area were weighted by the number of
31 medicare beneficiaries determined under paragraph
32 (2)(B), an aggregate total of 20 percent of the total of
33 the medicare beneficiaries determined under such para-
34 graph.

35 There is no administrative or judicial review respecting the
36 identification of a county or area or the assignment of a
37 specialty of any physician under this paragraph.



1 “(5) RURAL CENSUS TRACKS.—To the extent feasible,
2 the Secretary shall treat a rural census tract of a metro-
3 politan statistical area (as determined under the most re-
4 cent modification of the Goldsmith Modification, originally
5 published in the Federal Register on February 27, 1992
6 (57 Fed. Reg. 6725) as an equivalent area for purposes of
7 qualifying as a primary care scarcity county or specialist
8 care scarcity county under this subsection.

9 “(6) PHYSICIAN DEFINED.—For purposes of this
10 paragraph, the term ‘physician’ means a physician de-
11 scribed in section 1861(r)(1) and the term ‘primary care
12 physician’ means a physician who is identified in the avail-
13 able data as a general practitioner, family practice practi-
14 tioner, general internist, or obstetrician or gynecologist.

15 “(7) PUBLICATION OF LIST OF COUNTIES.—In car-
16 rying out this subsection for a year, the Secretary shall in-
17 clude, as part of the proposed and final rule to implement
18 the physician fee schedule under section 1848 for the year,
19 a list of all areas which will qualify as a primary care scar-
20 city county or specialist care scarcity county under this
21 subsection for the year involved.”.

22 (2) EFFECTIVE DATE.—The amendments made by
23 subsection (a) shall apply to physicians’ services furnished
24 or after January 1, 2004.

25 (b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT
26 PROGRAM.—

27 (1) IN GENERAL.—Section 1833(m) (42 U.S.C.
28 1395l(m)) is amended—

29 (A) by inserting “(1)” after “(m)”; and

30 (B) by adding at the end the following new para-
31 graphs:

32 “(2) The Secretary shall establish procedures under which
33 the Secretary, and not the physician furnishing the service, is
34 responsible for determining when a payment is required to be
35 made under paragraph (1).

36 “(3) In carrying out paragraph (1) for a year, the Sec-
37 retary shall include, as part of the proposed and final rule to



1 implement the physician fee schedule under section 1848 for
2 the year, a list of all areas which will qualify as a health profes-
3 sional shortage area under paragraph (1) for the year in-
4 volved.”.

5 (2) EFFECTIVE DATE.—The amendments made by
6 paragraph (1) shall apply to physicians’ services furnished
7 or after January 1, 2004.

8 **SEC. 418. MEDICARE INPATIENT HOSPITAL PAYMENT**
9 **ADJUSTMENT FOR LOW-VOLUME HOSPITALS.**

10 Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by
11 adding at the end the following new paragraph:

12 “(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOS-
13 PITALS.—

14 “(A) PAYMENT ADJUSTMENT.—

15 “(i) IN GENERAL.—Notwithstanding any other
16 provision of this section, for each cost reporting pe-
17 riod (beginning with the cost reporting period that
18 begins in fiscal year 2004), the Secretary shall pro-
19 vide for an additional payment amount to each low-
20 volume hospital (as defined in clause (iii)) for dis-
21 charges occurring during that cost reporting period
22 which is equal to the applicable percentage increase
23 (determined under clause (ii)) in the amount paid
24 to such hospital under this section for such dis-
25 charges.

26 “(ii) APPLICABLE PERCENTAGE INCREASE.—
27 The Secretary shall determine a percentage in-
28 crease applicable under this paragraph that ensures
29 that—

30 “(I) no percentage increase in payments
31 under this paragraph exceeds 25 percent of the
32 amount of payment that would (but for this
33 paragraph) otherwise be made to a low-volume
34 hospital under this section for each discharge;

35 “(II) low-volume hospitals that have the
36 lowest number of discharges during a cost re-
37 porting period receive the highest percentage



1 increases in payments due to the application of
2 this paragraph; and

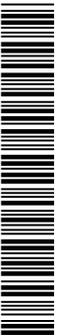
3 “(III) the percentage increase in payments
4 to any low-volume hospital due to the applica-
5 tion of this paragraph is reduced as the num-
6 ber of discharges per cost reporting period in-
7 creases.

8 “(iii) LOW-VOLUME HOSPITAL DEFINED.—For
9 purposes of this paragraph, the term ‘low-volume
10 hospital’ means, for a cost reporting period, a sub-
11 section (d) hospital (as defined in paragraph
12 (1)(B)) other than a critical access hospital (as de-
13 fined in section 1861(mm)(1)) that—

14 “(I) the Secretary determines had an aver-
15 age of less than 2,000 discharges (determined
16 with respect to all patients and not just individ-
17 uals receiving benefits under this title) during
18 the 3 most recent cost reporting periods for
19 which data are available that precede the cost
20 reporting period to which this paragraph ap-
21 plies; and

22 “(II) is located at least 15 miles from a
23 like hospital (or is deemed by the Secretary to
24 be so located by reason of such factors as the
25 Secretary determines appropriate, including the
26 time required for an individual to travel to the
27 nearest alternative source of appropriate inpa-
28 tient care (after taking into account the loca-
29 tion of such alternative source of inpatient care
30 and any weather or travel conditions that may
31 affect such travel time).

32 “(B) PROHIBITING CERTAIN REDUCTIONS.—Not-
33 withstanding subsection (e), the Secretary shall not re-
34 duce the payment amounts under this section to offset
35 the increase in payments resulting from the application
36 of subparagraph (A).”



1 **SEC. 419. TREATMENT OF CERTAIN CLINICAL DIAG-**
2 **NOSTIC LABORATORY TESTS FURNISHED BY**
3 **A SOLE COMMUNITY HOSPITAL.**

4 Notwithstanding subsections (a), (b), and (h) of section
5 1833 of the Social Security Act (42 U.S.C. 1395l) and section
6 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in the case
7 of a clinical diagnostic laboratory test covered under part B of
8 title XVIII of such Act that is furnished in 2004 or 2005 by
9 a sole community hospital (as defined in section
10 1886(d)(5)(D)(iii) of such Act (42 U.S.C.
11 1395ww(d)(5)(D)(iii))) as part of services furnished to patients
12 of the hospital, the following rules shall apply:

13 (1) PAYMENT BASED ON REASONABLE COSTS.—The
14 amount of payment for such test shall be 100 percent of
15 the reasonable costs of the hospital in furnishing such test.

16 (2) NO BENEFICIARY COST-SHARING.—Notwith-
17 standing section 432, no coinsurance, deductible, copay-
18 ment, or other cost-sharing otherwise applicable under such
19 part B shall apply with respect to such test.

20 **SEC. 420. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC**
21 **ADJUSTMENTS OF PAYMENTS FOR PHYSI-**
22 **CIANS' SERVICES.**

23 Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)) is
24 amended—

25 (1) in subparagraph (A), by striking “subparagraphs
26 (B) and (C)” and inserting “subparagraphs (B), (C), (E),
27 and (F)”; and

28 (2) by adding at the end the following new subpara-
29 graphs:

30 “(E) FLOOR FOR WORK GEOGRAPHIC INDICES.—

31 “(i) IN GENERAL.—For purposes of payment
32 for services furnished on or after January 1, 2004,
33 and before January 1, 2008, after calculating the
34 work geographic indices in subparagraph (A)(iii),
35 the Secretary shall increase the work geographic
36 index to the work floor index for any locality for
37 which such geographic index is less than the work
38 floor index.



1 “(ii) WORK FLOOR INDEX.—For purposes of
2 clause (i), the term ‘applicable floor index’ means—

3 “(I) 0.980 with respect to services fur-
4 nished during 2004; and

5 “(II) 1.000 for services furnished during
6 2005, 2006, and 2007.

7 “(F) FLOOR FOR PRACTICE EXPENSE AND MAL-
8 PRACTICE GEOGRAPHIC INDICES.—For purposes of
9 payment for services furnished on or after January 1,
10 2005, and before January 1, 2008, after calculating
11 the practice expense and malpractice indices in clauses
12 (i) and (ii) of subparagraph (A) and in subparagraph
13 (B), the Secretary shall increase any such index to 1.00
14 for any locality for which such index is less than 1.00.

15 **SEC. 421. AMBULANCE PAYMENT RATES.**

16 (a) PAYMENT RATES.—Section 1834(l)(3) (42 U.S.C.
17 1395m(l)(3)) is amended to read as follows:

18 “(3) PAYMENT RATES.—

19 “(A) IN GENERAL.—Subject to any adjustment
20 under subparagraph (B) and paragraph (9) and the
21 full payment of a national mileage rate pursuant to
22 subparagraph (2)(E), in establishing such fee schedule,
23 the following rules shall apply:

24 “(i) PAYMENT RATES IN 2003.—

25 “(I) GROUND AMBULANCE SERVICES.—In
26 the case of ground ambulance services fur-
27 nished under this part in 2003, the Secretary
28 shall set the payment rates under the fee
29 schedule for such services at a rate based on
30 the average costs (as determined by the Sec-
31 retary on the basis of the most recent and reli-
32 able information available) incurred by full cost
33 ambulance suppliers in providing nonemergency
34 basic life support ambulance services covered
35 under this title, with adjustments to the rates
36 for other ground ambulance service levels to be
37 determined based on the rule established under



1 paragraph (1). For the purposes of the pre-
2 ceding sentence, the term ‘full cost ambulance
3 supplier’ means a supplier for which volunteers
4 or other unpaid staff comprise less than 20
5 percent of the supplier’s total staff and which
6 receives less than 20 percent of space and other
7 capital assets free of charge.

8 “(II) OTHER AMBULANCE SERVICES.—In
9 the case of ambulance services not described in
10 subclause (I) that are furnished under this part
11 in 2003, the Secretary shall set the payment
12 rates under the fee schedule for such services
13 based on the rule established under paragraph
14 (1).

15 “(ii) PAYMENT RATES IN SUBSEQUENT YEARS
16 FOR ALL AMBULANCE SERVICES.—In the case of
17 any ambulance service furnished under this part in
18 2004 or any subsequent year, the Secretary shall
19 set the payment rates under the fee schedule for
20 such service at amounts equal to the payment rate
21 under the fee schedule for that service furnished
22 during the previous year, increased by the percent-
23 age increase in the Consumer Price Index for all
24 urban consumers (United States city average) for
25 the 12-month period ending with June of the pre-
26 vious year.

27 “(B) ADJUSTMENT IN RURAL RATES.—For years
28 beginning with 2004, the Secretary, after taking into
29 consideration the recommendations contained in the re-
30 port submitted under section 221(b)(3) the Medicare,
31 Medicaid, and SCHIP Benefits Improvements and Pro-
32 tection Act of 2000, shall adjust the fee schedule pay-
33 ment rates that would otherwise apply under this sub-
34 section for ambulance services provided in low density
35 rural areas based on the increased cost (if any) of pro-
36 viding such services in such areas.”



1 (b) CONFORMING AMENDMENT.—Section 221(c) of BIPA
2 is repealed.

3 **TITLE V—PROVISIONS RELATING**
4 **TO PART A**
5 **Subtitle A—Inpatient Hospital**
6 **Services**

7 **SEC. 501. ADJUSTMENT FOR INDIRECT COSTS OF MED-**
8 **ICAL EDUCATION (IME).**

9 Section 1886(d)(5)(B)(ii) (42 U.S.C. 1395ww(d)(5)(B)(ii))
10 is amended—

11 (1) by striking “and” at the end of subclause (VI);

12 (2) in subclause (VII)—

13 (A) by striking “on or after October 1, 2002,” and
14 inserting “during fiscal year 2003,”; and

15 (B) by striking the period at the end and inserting
16 “; and”; and

17 (3) by inserting after subclause (VII) the following
18 new subclauses:

19 “(VIII) during each of fiscal years 2004 and
20 2005, “c” is equal to 1.47; and

21 “(IX) on or after October 1, 2005, “c” is equal to
22 1.35.”.

23 **SEC. 502. RECOGNITION OF NEW MEDICAL TECH-**
24 **NOLOGIES UNDER INPATIENT HOSPITAL**
25 **PPS.**

26 (a) IMPROVING TIMELINESS OF DATA COLLECTION.—Sec-
27 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended
28 by adding at the end the following new clause:

29 “(vii) Under the mechanism under this subparagraph, the
30 Secretary shall provide for the addition of new diagnosis and
31 procedure codes in April 1 of each year, but the addition of
32 such codes shall not require the Secretary to adjust the pay-
33 ment (or diagnosis-related group classification) under this sub-
34 section until the fiscal year that begins after such date.”.

35 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY
36 OUTLIERS.—



1 (1) MINIMUM PERIOD FOR RECOGNITION OF NEW
2 TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
3 1395ww(d)(5)(K)(vi)) is amended—

4 (A) by inserting “(I)” after “(vi)”; and

5 (B) by adding at the end the following new sub-
6 clause:

7 “(II) Under such criteria, a service or technology shall not
8 be denied treatment as a new service or technology on the basis
9 of the period of time in which the service or technology has
10 been in use if such period ends before the end of the 2-to-3-
11 year period that begins on the effective date of implementation
12 of a code under ICD–9–CM (or a successor coding method-
13 ology) that enables the identification of specific discharges in
14 which the service or technology has been used.”.

15 (2) ADJUSTMENT OF THRESHOLD.—Section
16 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is
17 amended by inserting “(applying a threshold specified by
18 the Secretary that is 75 percent of one standard deviation
19 for the diagnosis-related group involved)” after “is inad-
20 equate”.

21 (3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—
22 Section 1886(d)(5)(K)(vi) (42 U.S.C.
23 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is
24 further amended by adding at the end the following sub-
25 clause:

26 “(III) The Secretary shall by regulation provide for fur-
27 ther clarification of the criteria applied to determine whether
28 a new service or technology represents an advance in medical
29 technology that substantially improves the diagnosis or treat-
30 ment of beneficiaries. Under such criteria, in determining
31 whether a new service or technology represents an advance in
32 medical technology that substantially improves the diagnosis or
33 treatment of beneficiaries, the Secretary shall deem a service
34 or technology as meeting such requirement if the service or
35 technology is a drug or biological that is designated under sec-
36 tion 506 of the Federal Food, Drug, and Cosmetic Act, ap-
37 proved under section 314.510 or 601.41 of title 21, Code of



1 Federal Regulations, or designated for priority review when the
2 marketing application for such drug or biological was filed or
3 is a medical device for which an exemption has been granted
4 under section 520(m) of such Act, or for which priority review
5 has been provided under section 515(d)(5) of such Act. Noth-
6 ing in this subclause shall be construed as effecting the author-
7 ity of the Secretary to determine whether items and services
8 are medically necessary and appropriate under section
9 1862(a)(1).”.

10 (4) PROCESS FOR PUBLIC INPUT.—Section
11 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended
12 by paragraph (1), is amended—

13 (A) in clause (i), by adding at the end the fol-
14 lowing: “Such mechanism shall be modified to meet the
15 requirements of clause (viii).”; and

16 (B) by adding at the end the following new clause:

17 “(viii) The mechanism established pursuant to clause (i)
18 shall be adjusted to provide, before publication of a proposed
19 rule, for public input regarding whether a new service or tech-
20 nology not described in the second sentence of clause (vi)(III)
21 represents an advance in medical technology that substantially
22 improves the diagnosis or treatment of beneficiaries as follows:

23 “(I) The Secretary shall make public and periodically
24 update a list of all the services and technologies for which
25 an application for additional payment under this subpara-
26 graph is pending.

27 “(II) The Secretary shall accept comments, rec-
28 ommendations, and data from the public regarding whether
29 the service or technology represents a substantial improve-
30 ment.

31 “(III) The Secretary shall provide for a meeting at
32 which organizations representing hospitals, physicians,
33 medicare beneficiaries, manufacturers, and any other inter-
34 ested party may present comments, recommendations, and
35 data to the clinical staff of the Centers for Medicare &
36 Medicaid Services before publication of a notice of proposed



1 rulemaking regarding whether service or technology rep-
2 represents a substantial improvement.”.

3 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Sec-
4 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further
5 amended by adding at the end the following new clause:

6 “(ix) Before establishing any add-on payment under this
7 subparagraph with respect to a new technology, the Secretary
8 shall seek to identify one or more diagnosis-related groups as-
9 sociated with such technology, based on similar clinical or ana-
10 tomical characteristics and the cost of the technology. Within
11 such groups the Secretary shall assign an eligible new tech-
12 nology into a diagnosis-related group where the average costs
13 of care most closely approximate the costs of care of using the
14 new technology. In such case, the new technology would no
15 longer meet the threshold of exceeding 75 percent of the stand-
16 ard deviation for the diagnosis-related group involved under
17 clause (ii)(I). No add-on payment under this subparagraph
18 shall be made with respect to such new technology and this
19 clause shall not affect the application of paragraph
20 (4)(C)(iii).”.

21 (d) IMPROVEMENT IN PAYMENT FOR NEW TECH-
22 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
23 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after “the
24 estimated average cost of such service or technology” the fol-
25 lowing: “(based on the marginal rate applied to costs under
26 subparagraph (A))”.

27 (e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL
28 INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42
29 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking “sub-
30 ject to paragraph (4)(C)(iii),”.

31 (f) EFFECTIVE DATE.—

32 (1) IN GENERAL.—The Secretary shall implement the
33 amendments made by this section so that they apply to
34 classification for fiscal years beginning with fiscal year
35 2005.

36 (2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL
37 YEAR 2003 THAT ARE DENIED.—In the case of an applica-



1 tion for a classification of a medical service or technology
2 as a new medical service or technology under section
3 1886(d)(5)(K) of the Social Security Act (42 U.S.C.
4 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and
5 that is denied—

6 (A) the Secretary shall automatically reconsider
7 the application as an application for fiscal year 2005
8 under the amendments made by this section; and

9 (B) the maximum time period otherwise permitted
10 for such classification of the service or technology shall
11 be extended by 12 months.

12 **SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS**
13 **IN PUERTO RICO.**

14 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
15 amended—

16 (1) in subparagraph (A)—

17 (A) in clause (i), by striking “for discharges begin-
18 ning on or after October 1, 1997, 50 percent (and for
19 discharges between October 1, 1987, and September
20 30, 1997, 75 percent)” and inserting “the applicable
21 Puerto Rico percentage (specified in subparagraph
22 (E))”; and

23 (B) in clause (ii), by striking “for discharges be-
24 ginning in a fiscal year beginning on or after October
25 1, 1997, 50 percent (and for discharges between Octo-
26 ber 1, 1987, and September 30, 1997, 25 percent)”
27 and inserting “the applicable Federal percentage (spec-
28 ified in subparagraph (E))”; and

29 (2) by adding at the end the following new subpara-
30 graph:

31 “(E) For purposes of subparagraph (A), for discharges
32 occurring—

33 “(i) on or after October 1, 1987, and before October
34 1, 1997, the applicable Puerto Rico percentage is 75 per-
35 cent and the applicable Federal percentage is 25 percent;



1 “(ii) on or after October 1, 1997, and before October
2 1, 2003, the applicable Puerto Rico percentage is 50 per-
3 cent and the applicable Federal percentage is 50 percent;

4 “(iii) during fiscal year 2004, the applicable Puerto
5 Rico percentage is 41 percent and the applicable Federal
6 percentage is 59 percent;

7 “(iv) during fiscal year 2005, the applicable Puerto
8 Rico percentage is 33 percent and the applicable Federal
9 percentage is 67 percent; and

10 “(v) on or after October 1, 2005, the applicable Puer-
11 to Rico percentage is 25 percent and the applicable Federal
12 percentage is 75 percent.”.

13 **SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICA-**
14 **TION REFORM .**

15 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
16 1395ww(d)) is amended by adding at the end the following:

17 “(11)(A) In order to recognize commuting patterns among
18 Metropolitan Statistical Areas and between such Areas and
19 rural areas, the Secretary shall establish a process, upon appli-
20 cation of a subsection (d) hospital that establishes that it is a
21 qualifying hospital described in subparagraph (B), for an in-
22 crease of the wage index applied under paragraph (3)(E) for
23 the hospital in the amount computed under subparagraph (D).

24 “(B) A qualifying hospital described in this subparagraph
25 is a subsection (d) hospital—

26 “(i) the average wages of which exceed the average
27 wages for the area in which the hospital is located; and

28 “(ii) which has at least 10 percent of its employees
29 who reside in one or more higher wage index areas.

30 “(C) For purposes of this paragraph, the term ‘higher
31 wage index area’ means, with respect to a hospital, an area
32 with a wage index that exceeds that of the area in which the
33 hospital is located.

34 “(D) The increase in the wage index under subparagraph
35 (A) for a hospital shall be equal to the percentage of the em-
36 ployees of the hospital that resides in any higher wage index



1 area multiplied by the sum of the products, for each higher
2 wage index area of—

3 “(i) the difference between (I) the wage index for such
4 area, and (II) the wage index of the area in which the hos-
5 pital is located (before the application of this paragraph);
6 and

7 “(ii) the number of employees of the hospital that re-
8 side in such higher wage index area divided by the total
9 number of such employees that reside in all high wage
10 index areas.

11 “(E) The process under this paragraph shall be based
12 upon the process used by the Medicare Geographic Classifica-
13 tion Review Board under paragraph (10) with respect to data
14 submitted by hospitals to the Board on the location of resi-
15 dence of hospital employees and wages under the applicable
16 schedule established for geographic reclassification.

17 “(F) A reclassification under this paragraph shall be effec-
18 tive for a period of 3 fiscal years, except that the Secretary
19 shall establish procedures under which a subsection (d) hospital
20 may elect to terminate such reclassification before the end of
21 such period.

22 “(G) A hospital that is reclassified under this paragraph
23 for a period is not eligible for reclassification under paragraphs
24 (8) or (10) during that period.

25 “(H) Any increase in a wage index under this paragraph
26 for a hospital shall not be taken into account for purposes of—

27 “(i) computing the wage index for the area in which
28 the hospital is located or any other area; or

29 “(ii) applying any budget neutrality adjustment with
30 respect to such index under paragraph (8)(D).”.

31 (b) EFFECTIVE DATE.—The amendment made by sub-
32 section (a) shall first apply to the wage index for cost reporting
33 period beginning on or after October 1, 2004.



1 **SEC. 505. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**
2 **MEDICARE LIMITS ON PHYSICIAN REFER-**
3 **RALS.**

4 (a) OWNERSHIP AND INVESTMENT INTERESTS IN WHOLE
5 HOSPITALS.—

6 (1) IN GENERAL.—Section 1877(d)(3) (42 U.S.C.
7 1395nn(d)(3)) is amended—

8 (A) by striking “and” at the end of subparagraph
9 (A); and

10 (B) by redesignating subparagraph (B) as sub-
11 paragraph (C) and inserting after subparagraph (A)
12 the following:

13 “(B) the hospital is not a specialty hospital (as de-
14 fined in subsection (h)(7)); and”.

15 (2) DEFINITION.—Section 1877(h) (42 U.S.C.
16 1395nn(h)) is amended by adding at the end the following:

17 “(7) SPECIALTY HOSPITAL.—

18 “(A) IN GENERAL.—For purposes of this section,
19 except as provided in subparagraph (B), the term ‘spe-
20 cialty hospital’ means a hospital that is primarily or ex-
21 clusively engaged in the care and treatment of one of
22 the following:

23 “(i) patients with a cardiac condition;

24 “(ii) patients with an orthopedic condition;

25 “(iii) patients receiving a surgical procedure;

26 or

27 “(iv) any other specialized category of patients
28 or cases that the Secretary designates as incon-
29 sistent with the purpose of permitting physician
30 ownership and investment interests in a hospital
31 under this section.

32 “(B) EXCEPTION.—For purposes of this section,
33 the term ‘specialty hospital’ does not include any
34 hospital—

35 “(i) determined by the Secretary—

36 “(I) to be in operation before June 12,
37 2003; or



1 “(II) under development as of such date;
2 “(ii) for which the number of beds and the
3 number of physician investors at any time on or
4 after such date is no greater than the number of
5 such beds or investors as of such date; and
6 “(iii) that meets such other requirements as
7 the Secretary may specify.”.

8 (b) EFFECTIVE DATE.—Subject to subsection (c), the
9 amendments made by this section shall apply to referrals made
10 for designated health services on or after January 1, 2004.

11 (c) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER
12 DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II)
13 of the Social Security Act, as added by subsection (a)(2), in de-
14 termining whether a hospital is under development as of June
15 12, 2003, the Secretary shall consider—

16 (1) whether architectural plans have been completed,
17 funding has been received, zoning requirements have been
18 met, and necessary approvals from appropriate State agen-
19 cies have been received; and

20 (2) any other evidence the Secretary determines would
21 indicate whether a hospital is under development as of such
22 date.

23 **Subtitle B—Other Provisions**

24 **SEC. 511. PAYMENT FOR COVERED SKILLED NURSING** 25 **FACILITY SERVICES.**

26 (a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—
27 Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is
28 amended to read as follows:

29 “(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—
30 “(A) IN GENERAL.—Subject to subparagraph (B),
31 in the case of a resident of a skilled nursing facility
32 who is afflicted with acquired immune deficiency syn-
33 drome (AIDS), the per diem amount of payment other-
34 wise applicable shall be increased by 128 percent to re-
35 flect increased costs associated with such residents.

36 “(B) SUNSET.—Subparagraph (A) shall not apply
37 on and after such date as the Secretary certifies that



1 there is an appropriate adjustment in the case mix
2 under paragraph (4)(G)(i) to compensate for the in-
3 creased costs associated with residents described in
4 such subparagraph.”.

5 (b) EFFECTIVE DATE.—The amendment made by para-
6 graph (1) shall apply to services furnished on or after October
7 1, 2003.

8 **SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERV-**
9 **ICES.**

10 (a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—
11 Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

12 (1) by striking “and” at the end of paragraph (3);

13 (2) by striking the period at the end of paragraph (4)
14 and inserting “; and”; and

15 (3) by inserting after paragraph (4) the following new
16 paragraph:

17 “(5) for individuals who are terminally ill, have not
18 made an election under subsection (d)(1), and have not
19 previously received services under this paragraph, services
20 that are furnished by a physician who is either the medical
21 director or an employee of a hospice program and that con-
22 sist of—

23 “(A) an evaluation of the individual’s need for
24 pain and symptom management;

25 “(B) counseling the individual with respect to end-
26 of-life issues and care options; and

27 “(C) advising the individual regarding advanced
28 care planning.”.

29 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is
30 amended by adding at the end the following new paragraph:

31 “(4) The amount paid to a hospice program with respect
32 to the services under section 1812(a)(5) for which payment
33 may be made under this part shall be equal to an amount
34 equivalent to the amount established for an office or other out-
35 patient visit for evaluation and management associated with
36 presenting problems of moderate severity under the fee sched-
37 ule established under section 1848(b), other than the portion



1 of such amount attributable to the practice expense compo-
2 nent.”.

3 (c) CONFORMING AMENDMENT.—Section
4 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended
5 by inserting before the comma at the end the following: “and
6 services described in section 1812(a)(5)”.

7 (d) EFFECTIVE DATE.—The amendments made by this
8 section shall apply to services provided by a hospice program
9 on or after January 1, 2004.

10 **TITLE VI—PROVISIONS RELATING**
11 **TO PART B**
12 **Subtitle A—Physicians’ Services**

13 **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS’**
14 **SERVICES.**

15 (a) UPDATE FOR 2004 AND 2005.—

16 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
17 1395w-4(d)) is amended by adding at the end the following
18 new paragraph:

19 “(5) UPDATE FOR 2004 AND 2005.—The update to the
20 single conversion factor established in paragraph (1)(C) for
21 each of 2004 and 2005 shall be not less than 1.5 percent.”.

22 (2) CONFORMING AMENDMENT.—Paragraph (4)(B) of
23 such section is amended, in the matter before clause (i), by
24 inserting “and paragraph (5)” after “subparagraph (D)”.

25 (3) NOT TREATED AS CHANGE IN LAW AND REGULA-
26 TION IN SUSTAINABLE GROWTH RATE DETERMINATION.—
27 The amendments made by this subsection shall not be
28 treated as a change in law for purposes of applying section
29 1848(f)(2)(D) of the Social Security Act (42 U.S.C.
30 1395w-4(f)(2)(D)).

31 (b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING
32 GROSS DOMESTIC PRODUCT.—

33 (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C.
34 1395w-4(f)(2)(C)) is amended—

35 (A) by striking “projected” and inserting “annual
36 average”; and



1 (B) by striking “from the previous applicable pe-
2 riod to the applicable period involved” and inserting
3 “during the 10-year period ending with the applicable
4 period involved”.

5 (2) EFFECTIVE DATE.—The amendment made by
6 paragraph (1) shall apply to computations of the sustain-
7 able growth rate for years beginning with 2003.

8 **SEC. 602. STUDIES ON ACCESS TO PHYSICIANS’ SERV-**
9 **ICES.**

10 (a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSI-
11 CIANS’ SERVICES.—

12 (1) STUDY.—The Comptroller General of the United
13 States shall conduct a study on access of medicare bene-
14 ficiaries to physicians’ services under the medicare pro-
15 gram. The study shall include—

16 (A) an assessment of the use by beneficiaries of
17 such services through an analysis of claims submitted
18 by physicians for such services under part B of the
19 medicare program;

20 (B) an examination of changes in the use by bene-
21 ficiaries of physicians’ services over time;

22 (C) an examination of the extent to which physi-
23 cians are not accepting new medicare beneficiaries as
24 patients.

25 (2) REPORT.—Not later than 18 months after the
26 date of the enactment of this Act, the Comptroller General
27 shall submit to Congress a report on the study conducted
28 under paragraph (1). The report shall include a determina-
29 tion whether—

30 (A) data from claims submitted by physicians
31 under part B of the medicare program indicate poten-
32 tial access problems for medicare beneficiaries in cer-
33 tain geographic areas; and

34 (B) access by medicare beneficiaries to physicians’
35 services may have improved, remained constant, or de-
36 teriorated over time.

37 (b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—



1 (1) STUDY.—The Secretary shall request the Institute
2 of Medicine of the National Academy of Sciences to con-
3 duct a study on the adequacy of the supply of physicians
4 (including specialists) in the United States and the factors
5 that affect such supply.

6 (2) REPORT TO CONGRESS.—Not later than 2 years
7 after the date of enactment of this section, the Secretary
8 shall submit to Congress a report on the results of the
9 study described in paragraph (1), including any rec-
10 ommendations for legislation.

11 (c) GAO STUDY OF MEDICARE PAYMENT FOR INHALA-
12 TION THERAPY.—

13 (1) STUDY.—The Comptroller General of the United
14 States shall conduct a study to examine the adequacy of
15 current reimbursements for inhalation therapy under the
16 medicare program.

17 (2) REPORT.—Not later than May 1, 2004, the Comp-
18 troller General shall submit to Congress a report on the
19 study conducted under paragraph (1).

20 **SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSI-**
21 **CIANS' SERVICES.**

22 (a) PRACTICE EXPENSE COMPONENT.—Not later than 1
23 year after the date of the enactment of this Act, the Medicare
24 Payment Advisory Commission shall submit to Congress a re-
25 port on the effect of refinements to the practice expense compo-
26 nent of payments for physicians' services, after the transition
27 to a full resource-based payment system in 2002, under section
28 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such re-
29 port shall examine the following matters by physician specialty:

30 (1) The effect of such refinements on payment for
31 physicians' services.

32 (2) The interaction of the practice expense component
33 with other components of and adjustments to payment for
34 physicians' services under such section.

35 (3) The appropriateness of the amount of compensa-
36 tion by reason of such refinements.



1 (4) The effect of such refinements on access to care
2 by medicare beneficiaries to physicians' services.

3 (5) The effect of such refinements on physician par-
4 ticipation under the medicare program.

5 (b) VOLUME OF PHYSICIAN SERVICES.—The Medicare
6 Payment Advisory Commission shall submit to Congress a re-
7 port on the extent to which increases in the volume of physi-
8 cians' services under part B of the medicare program are a re-
9 sult of care that improves the health and well-being of medicare
10 beneficiaries. The study shall include the following:

11 (1) An analysis of recent and historic growth in the
12 components that the Secretary includes under the sustain-
13 able growth rate (under section 1848(f) of the Social Secu-
14 rity Act).

15 (2) An examination of the relative growth of volume
16 in physician services between medicare beneficiaries and
17 other populations.

18 (3) An analysis of the degree to which new technology,
19 including coverage determinations of the Centers for Medi-
20 care & Medicaid Services, has affected the volume of physi-
21 cians' services.

22 (4) An examination of the impact on volume of demo-
23 graphic changes.

24 (5) An examination of shifts in the site of service of
25 services that influence the number and intensity of services
26 furnished in physicians' offices and the extent to which
27 changes in reimbursement rates to other providers have af-
28 fected these changes.

29 (6) An evaluation of the extent to which the Centers
30 for Medicare & Medicaid Services takes into account the
31 impact of law and regulations on the sustainable growth
32 rate.

33 **Subtitle B—Preventive Services**

34 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-**
35 **ICAL EXAMINATION.**

36 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
37 1395x(s)(2)) is amended—



1 (1) in subparagraph (U), by striking “and” at the
2 end;

3 (2) in subparagraph (V), by inserting “and” at the
4 end; and

5 (3) by adding at the end the following new subpara-
6 graph:

7 “(W) an initial preventive physical examination (as de-
8 fined in subsection (ww));”.

9 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
10 1395x) is amended by adding at the end the following new sub-
11 section:

12 “Initial Preventive Physical Examination

13 “(ww) The term ‘initial preventive physical examination’
14 means physicians’ services consisting of a physical examination
15 with the goal of health promotion and disease detection and in-
16 cludes items and services (excluding clinical laboratory tests),
17 as determined by the Secretary, consistent with the rec-
18 ommendations of the United States Preventive Services Task
19 Force.”.

20 (c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

21 (1) DEDUCTIBLE.—The first sentence of section
22 1833(b) (42 U.S.C. 1395l(b)) is amended—

23 (A) by striking “and” before “(6)”, and

24 (B) by inserting before the period at the end the
25 following: “, and (7) such deductible shall not apply
26 with respect to an initial preventive physical examina-
27 tion (as defined in section 1861(ww))”.

28 (2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C.
29 1395l(a)(1)) is amended—

30 (A) in clause (N), by inserting “(or 100 percent
31 in the case of an initial preventive physical examina-
32 tion, as defined in section 1861(ww))” after “80 per-
33 cent”; and

34 (B) in clause (O), by inserting “(or 100 percent
35 in the case of an initial preventive physical examina-
36 tion, as defined in section 1861(ww))” after “80 per-
37 cent”.



1 (d) PAYMENT AS PHYSICIANS' SERVICES.—Section
2 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by inserting
3 “(2)(W),” after “(2)(S),”.

4 (e) OTHER CONFORMING AMENDMENTS.—Section 1862(a)
5 (42 U.S.C. 1395y(a)) is amended—

6 (1) in paragraph (1)—

7 (A) by striking “and” at the end of subparagraph
8 (H);

9 (B) by striking the semicolon at the end of sub-
10 paragraph (I) and inserting “, and”; and

11 (C) by adding at the end the following new sub-
12 paragraph:

13 “(J) in the case of an initial preventive physical exam-
14 ination, which is performed not later than 6 months after
15 the date the individual’s first coverage period begins under
16 part B;”; and

17 (2) in paragraph (7), by striking “or (H)” and insert-
18 ing “(H), or (J)”.

19 (f) EFFECTIVE DATE.—The amendments made by this
20 section shall apply to services furnished on or after January 1,
21 2004, but only for individuals whose coverage period begins on
22 or after such date.

23 **SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD**
24 **LIPID SCREENING.**

25 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
26 1395x(s)(2)), as amended by section 611(a), is amended—

27 (1) in subparagraph (V), by striking “and” at the end;

28 (2) in subparagraph (W), by inserting “and” at the
29 end; and

30 (3) by adding at the end the following new subpara-
31 graph:

32 “(X) cholesterol and other blood lipid screening
33 tests (as defined in subsection (XX));”.

34 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
35 1395x), as amended by section 611(b), is amended by adding
36 at the end the following new subsection:



1 “Cholesterol and Other Blood Lipid Screening Test

2 “(xx)(1) The term ‘cholesterol and other blood lipid
3 screening test’ means diagnostic testing of cholesterol and other
4 lipid levels of the blood for the purpose of early detection of
5 abnormal cholesterol and other lipid levels.

6 “(2) The Secretary shall establish standards, in consulta-
7 tion with appropriate organizations, regarding the frequency
8 and type of cholesterol and other blood lipid screening tests, ex-
9 cept that such frequency may not be more often than once
10 every 2 years.”.

11 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
12 1395y(a)(1)), as amended by section 611(e), is amended—

13 (1) by striking “and” at the end of subparagraph (I);

14 (2) by striking the semicolon at the end of subpara-
15 graph (J) and inserting “; and”; and

16 (3) by adding at the end the following new subpara-
17 graph:

18 “(K) in the case of a cholesterol and other blood lipid
19 screening test (as defined in section 1861(xx)(1)), which is
20 performed more frequently than is covered under section
21 1861(xx)(2).”.

22 (d) EFFECTIVE DATE.—The amendments made by this
23 section shall apply to tests furnished on or after January 1,
24 2005.

25 **SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL**
26 **CANCER SCREENING TESTS.**

27 (a) IN GENERAL.—The first sentence of section 1833(b)
28 (42 U.S.C. 1395l(b)), as amended by section 611(e)(1), is
29 amended—

30 (1) by striking “and” before “(7)”; and

31 (2) by inserting before the period at the end the fol-
32 lowing: “, and (8) such deductible shall not apply with re-
33 spect to colorectal cancer screening tests (as described in
34 section 1861(pp)(1))”.

35 (b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii)
36 and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are
37 each amended—



1 (1) by striking “DEDUCTIBLE AND” in the heading;
2 and
3 (2) in subclause (I), by striking “deductible or” each
4 place it appears.

5 (c) EFFECTIVE DATE.—The amendment made by this sec-
6 tion shall apply to items and services furnished on or after
7 January 1, 2004.

8 **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
9 **RAPHY SERVICES.**

10 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Section
11 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by
12 inserting before the period at the end the following: “and does
13 not include screening mammography (as defined in section
14 1861(jj)) and unilateral and bilateral diagnostic mammo-
15 graphy”.

16 (b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diag-
17 nostic mammography performed on or after January 1, 2004,
18 for which payment is made under the physician fee schedule
19 under section 1848 of the Social Security Act (42 U.S.C.
20 1395w-4), the Secretary, based on the most recent cost data
21 available, shall provide for an appropriate adjustment in the
22 payment amount for the technical component of the diagnostic
23 mammography.

24 (c) EFFECTIVE DATE.—The amendment made by sub-
25 section (a) shall apply to mammography performed on or after
26 January 1, 2004.

27 **Subtitle C—Other Services**

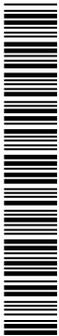
28 **SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD)**
29 **PAYMENT REFORM.**

30 (a) PAYMENT FOR DRUGS.—

31 (1) MODIFICATION OF AMBULATORY PAYMENT CLASSI-
32 FICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C.
33 1395l(t)) is amended—

34 (A) by redesignating paragraph (13) as paragraph
35 (14); and

36 (B) by inserting after paragraph (12) the fol-
37 lowing new paragraph:



1 “(13) DRUG APC PAYMENT RATES.—

2 “(A) IN GENERAL.—With respect to payment for
3 covered OPD services that includes a specified covered
4 outpatient drug (defined in subparagraph (B)), the
5 amount provided for payment for such drug under the
6 payment system under this subsection for services fur-
7 nished in—

8 “(i) 2004, 2005, or 2006, shall in no case—

9 “(I) exceed 95 percent of the average
10 wholesale price for the drug; or

11 “(II) be less than the transition percent-
12 age (under subparagraph (C)) of the average
13 wholesale price for the drug; or

14 “(ii) a subsequent year, shall be equal to the
15 average price for the drug for that area and year
16 established under the competitive acquisition pro-
17 gram under section 1847A as calculated and ap-
18 plied by the Secretary for purposes of this para-
19 graph.

20 “(B) SPECIFIED COVERED OUTPATIENT DRUG DE-
21 FINED.—

22 “(i) IN GENERAL.—In this paragraph, the
23 term ‘specified covered outpatient drug’ means,
24 subject to clause (ii), a covered outpatient drug (as
25 defined in 1927(k)(2), that is—

26 “(I) a radiopharmaceutical; or

27 “(II) a drug or biological for which pay-
28 ment was made under paragraph (6) (relating
29 to pass-through payments) on or before Decem-
30 ber 31, 2002.

31 “(ii) EXCEPTION.—Such term does not
32 include—

33 “(I) a drug for which payment is first
34 made on or after January 1, 2003, under para-
35 graph (6); or

36 “(II) a drug for a which a temporary
37 HCPCS code has not been assigned.



1 “(C) TRANSITION TOWARDS HISTORICAL AVERAGE
2 ACQUISITION COST.—The transition percentage under
3 this subparagraph for drugs furnished in a year is de-
4 termined in accordance with the following table:

The transition percentage for—

For the year—	Single source drugs are—	Innovator mul- tiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

5 “(D) PAYMENT FOR NEW DRUGS UNTIL TEM-
6 PORARY HCPCS CODE ASSIGNED.—With respect to
7 payment for covered OPD services that includes a cov-
8 ered outpatient drug (as defined in 1927(k)) for a
9 which a temporary HCPCS code has not been assigned,
10 the amount provided for payment for such drug under
11 the payment system under this subsection shall be
12 equal to 95 percent of the average wholesale price for
13 the drug.

14 “(E) CLASSES OF DRUGS.—For purposes of this
15 paragraph, each of the following shall be treated as a
16 separate class of drugs:

17 “(i) SOLE SOURCE DRUGS.—A sole source
18 drug which for purposes of this paragraph means
19 a drug or biological that is not a multiple source
20 drug (as defined in subclauses (I) and (II) of sec-
21 tion 1927(k)(7)(A)(i)) and is not a drug approved
22 under an abbreviated new drug application under
23 section 355(j) of the Federal Food, Drug, and Cos-
24 metic Act.

25 “(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—
26 Innovator multiple source drugs (as defined in sec-
27 tion 1927(k)(7)(A)(ii)).

28 “(iii) NONINNOVATOR MULTIPLE SOURCE
29 DRUGS.—Noninnovator multiple source drugs (as
30 defined in section 1927(k)(7)(A)(iii)).



1 “(F) INAPPLICABILITY OF EXPENDITURES IN DE-
2 TERMINING CONVERSION FACTORS.—Additional ex-
3 penditures resulting from this paragraph and para-
4 graph (14)(C) in a year shall not be taken into account
5 in establishing the conversion factor for that year.”.

6 (2) REDUCTION IN THRESHOLD FOR SEPARATE APCS
7 FOR DRUGS.—Section 1833(t)(14), as redesignated by
8 paragraph (1)(A), is amended by adding at the end the fol-
9 lowing new subparagraph:

10 “(B) THRESHOLD FOR ESTABLISHMENT OF SEPA-
11 RATE APCS FOR DRUGS.—The Secretary shall reduce
12 the threshold for the establishment of separate ambula-
13 tory procedure classification groups (APCs) with re-
14 spect to drugs to \$50 per administration.”.

15 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
16 OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by
17 adding at the end the following new subparagraph:

18 “(E) EXCLUSION OF SEPARATE DRUG APCS FROM
19 OUTLIER PAYMENTS.—No additional payment shall be
20 made under subparagraph (A) in the case of ambula-
21 tory procedure codes established separately for drugs.”.

22 (4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i)
23 of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is
24 amended by inserting after “under section 1842(o)” the
25 following: “(or if the drug is covered under a competitive
26 acquisition contract under section 1847A for an area, an
27 amount determined by the Secretary equal to the average
28 price for the drug for that area and year established under
29 such section as calculated and applied by the Secretary for
30 purposes of this paragraph)”.

31 (5) EFFECTIVE DATE.—The amendments made by
32 this subsection shall apply to services furnished on or after
33 January 1, 2004.

34 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

35 (1) IN GENERAL.—Section 1833(t)(14), as so redesign-
36 ated and amended by subsection (a)(2), is amended by
37 adding at the end the following new subparagraph:



1 “(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY
2 AT CHARGES ADJUSTED TO COST.—Notwithstanding
3 the preceding provisions of this subsection, for a device
4 of brachytherapy furnished on or after January 1,
5 2004, and before January 1, 2007, the payment basis
6 for the device under this subsection shall be equal to
7 the hospital’s charges for each device furnished, ad-
8 justed to cost.”.

9 (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY
10 DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is
11 amended—

12 (A) in subparagraph (F), by striking “and” at the
13 end;

14 (B) in subparagraph (G), by striking the period at
15 the end and inserting “; and”; and

16 (C) by adding at the end the following new sub-
17 paragraph:

18 “(H) with respect to devices of brachytherapy, the
19 Secretary shall create additional groups of covered
20 OPD services that classify such devices separately from
21 the other services (or group of services) paid for under
22 this subsection in a manner reflecting the number, iso-
23 tope, and radioactive intensity of such devices fur-
24 nished, including separate groups for palladium-103
25 and iodine-125 devices.”.

26 (3) GAO REPORT.—The Comptroller General of the
27 United States shall conduct a study to determine appro-
28 priate payment amounts under section 1833(t)(13)(B) of
29 the Social Security Act, as added by paragraph (1), for de-
30 vices of brachytherapy. Not later than January 1, 2005,
31 the Comptroller General shall submit to Congress and the
32 Secretary a report on the study conducted under this para-
33 graph, and shall include specific recommendations for ap-
34 propriate payments for such devices.

35 (c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—



1 (1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C.
2 1395l(t)(6)) is amended by adding at the end the following
3 new subparagraph:

4 “(F) LIMITATION ON APPLICATION OF FUNC-
5 TIONAL EQUIVALENCE STANDARD.—The Secretary may
6 not apply a ‘functional equivalence’ payment standard
7 (including such standard promulgated on November 1,
8 2002) or any other similar standard in order to deem
9 a particular drug or biological to be identical to or
10 similar to another drug or biological with respect to its
11 mechanism of action or clinical effect to deny pass-
12 through status to new drugs or biologics or to remove
13 such status of an existing eligible drug or biologic
14 under this paragraph unless—

15 “(i) the Secretary develops by regulation (after
16 providing notice and a period for public comment)
17 criteria for the application of such standard; and

18 “(ii) such criteria provide for coordination
19 with the Federal Food and Drug Administration
20 and require scientific studies that show the clinical
21 relationship between the drugs or biologicals treat-
22 ed as functionally equivalent.”.

23 (2) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall apply to the application of a functional
25 equivalence standard to a drug or biological on or after the
26 date of the enactment of this Act, unless such application
27 was being made to such drug or biological prior to June
28 13, 2003.

29 (d) HOSPITAL ACQUISITION COST STUDY.—

30 (1) IN GENERAL.—The Secretary shall conduct a
31 study on the costs incurred by hospitals in acquiring cov-
32 ered outpatient drugs for which payment is made under
33 section 1833(t) of the Social Security Act (42 U.S.C.
34 1395l(t)).

35 (2) DRUGS COVERED.—The study in paragraph (1)
36 shall not include those drugs for which the acquisition costs
37 is less than \$50 per administration.



1 (3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In
2 conducting the study under paragraph (1), the Secretary
3 shall collect data from a statistically valid sample of hos-
4 pitals with an urban/rural stratification.

5 (4) REPORT.—Not later than January 1, 2006, the
6 Secretary shall submit to Congress a report on the study
7 conducted under paragraph (1), and shall include rec-
8 ommendations with respect to the following:

9 (A) Whether the study should be repeated, and if
10 so, how frequently.

11 (B) Whether the study produced useful data on
12 hospital acquisition cost.

13 (C) Whether data produced in the study is appro-
14 priate for use in making adjustments to payments for
15 drugs and biologicals under section 1847A of the Social
16 Security Act.

17 (D) Whether separate estimates can made of over-
18 head costs, including handling and administering costs
19 for drugs.

20 **SEC. 622. PAYMENT FOR AMBULANCE SERVICES.**

21 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE
22 SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l)
23 (42 U.S.C. 1395m(l)), as amended by section 410(a), is
24 amended—

25 (1) in paragraph (2)(E), by inserting “consistent with
26 paragraph (11)” after “in an efficient and fair manner”;
27 and

28 (2) by adding at the end the following new paragraph:

29 “(11) PHASE-IN PROVIDING FLOOR USING BLEND OF
30 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In car-
31 rying out the phase-in under paragraph (2)(E) for each
32 level of service furnished in a year, the portion of the pay-
33 ment amount that is based on the fee schedule shall not
34 be less than the following blended rate of the fee schedule
35 under paragraph (1) and of a regional fee schedule for the
36 region involved:



1 “(A) For 2004, the blended rate shall be based 20
2 percent on the fee schedule under paragraph (1) and
3 80 percent on the regional fee schedule.

4 “(B) For 2005, the blended rate shall be based 40
5 percent on the fee schedule under paragraph (1) and
6 60 percent on the regional fee schedule.

7 “(C) For 2006, the blended rate shall be based 60
8 percent on the fee schedule under paragraph (1) and
9 40 percent on the regional fee schedule.

10 “(D) For 2007, 2008, and 2009, the blended rate
11 shall be based 80 percent on the fee schedule under
12 paragraph (1) and 20 percent on the regional fee
13 schedule.

14 “(E) For 2010 and each succeeding year, the
15 blended rate shall be based 100 percent on the fee
16 schedule under paragraph (1).

17 For purposes of this paragraph, the Secretary shall estab-
18 lish a regional fee schedule for each of the 9 Census divi-
19 sions using the methodology (used in establishing the fee
20 schedule under paragraph (1)) to calculate a regional con-
21 version factor and a regional mileage payment rate and
22 using the same payment adjustments and the same relative
23 value units as used in the fee schedule under such para-
24 graph.”.

25 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
26 TRIPS.—Section 1834(l), as amended by subsection (a), is fur-
27 ther amended by adding at the end the following new para-
28 graph:

29 “(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
30 TRIPS.—In the case of ground ambulance services fur-
31 nished on or after January 1, 2004, and before January 1,
32 2009, regardless of where the transportation originates, the
33 fee schedule established under this subsection shall provide
34 that, with respect to the payment rate for mileage for a
35 trip above 50 miles the per mile rate otherwise established
36 shall be increased by $\frac{1}{4}$ of the payment per mile otherwise
37 applicable to such miles.”.



1 (c) GAO REPORT ON COSTS AND ACCESS.—Not later than
2 December 31, 2005, the Comptroller General of the United
3 States shall submit to Congress an initial report on how costs
4 differ among the types of ambulance providers and on access,
5 supply, and quality of ambulance services in those regions and
6 States that have a reduction in payment under the medicare
7 ambulance fee schedule (under section 1834(l) of the Social Se-
8 curity Act, as amended by this section). Not later than Decem-
9 ber 31, 2007, the Comptroller General shall submit to Congress
10 a final report on such access and supply.

11 (d) EFFECTIVE DATE.—The amendments made by this
12 section shall apply to ambulance services furnished on or after
13 January 1, 2004.

14 **SEC. 623. RENAL DIALYSIS SERVICES.**

15 (a) DEMONSTRATION OF ALTERNATIVE DELIVERY MOD-
16 ELS.—

17 (1) USE OF ADVISORY BOARD.—In carrying out the
18 demonstration project relating to improving care for people
19 with end-stage renal disease through alternative delivery
20 models (as published in the Federal Register of June 4,
21 2003), the Secretary shall establish an advisory board com-
22 prised of representatives described in paragraph (2) to pro-
23 vide advice and recommendations with respect to the estab-
24 lishment and operation of such demonstration project.

25 (2) REPRESENTATIVES.—Representatives referred to
26 in paragraph (1) include representatives of the following:

27 (A) Patient organizations.

28 (B) Clinicians.

29 (C) The medicare payment advisory commission,
30 established under section 1805 of the Social Security
31 Act (42 U.S.C. 1395b–6).

32 (D) The National Kidney Foundation.

33 (E) The National Institute of Diabetes and Diges-
34 tive and Kidney Diseases of National Institutes of
35 Health.

36 (F) End-stage renal disease networks.



1 (G) Medicare contractors to monitor quality of
2 care.

3 (I) providers of services and renal dialysis facilities
4 furnishing end-stage renal disease services.

5 (J) Economists.

6 (K) Researchers.

7 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDI-
8 ATRIC FACILITIES.—

9 (1) IN GENERAL.—Section 422(a)(2) of BIPA is
10 amended—

11 (A) in subparagraph (A), by striking “and (C)”
12 and inserting “, (C), and (D)”;

13 (B) in subparagraph (B), by striking “In the
14 case” and inserting “Subject to subparagraph (D), in
15 the case”; and

16 (C) by adding at the end the following new sub-
17 paragraph:

18 “(D) INAPPLICABILITY TO PEDIATRIC FACILI-
19 TIES.—Subparagraphs (A) and (B) shall not apply, as
20 of October 1, 2002, to pediatric facilities that do not
21 have an exception rate described in subparagraph (C)
22 in effect on such date. For purposes of this subpara-
23 graph, the term ‘pediatric facility’ means a renal facil-
24 ity at least 50 percent of whose patients are individuals
25 under 18 years of age.”.

26 (2) CONFORMING AMENDMENT.—The fourth sentence
27 of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amend-
28 ed by subsection (b), is further amended by striking
29 “Until” and inserting “Subject to section 422(a)(2) of the
30 Medicare, Medicaid, and SCHIP Benefits Improvement and
31 Protection Act of 2000, and until”.

32 (c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR
33 SERVICES FURNISHED IN 2004.—Notwithstanding any other
34 provision of law, with respect to payment under part B of title
35 XVIII of the Social Security Act for renal dialysis services fur-
36 nished in 2004, the composite payment rate otherwise estab-



1 lished under section 1881(b)(7) of such Act (42 U.S.C.
2 1395rr(b)(7)) shall be increased by 1.6 percent.

3 **SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS;**
4 **PROVISIONS RELATING TO REPORTS.**

5 (a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section
6 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking
7 “and 2002” and inserting “2002, and 2004”.

8 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-
9 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-
10 ICES.—Not later than December 31, 2003, the Secretary shall
11 submit to Congress the reports required under section
12 4541(d)(2) of the Balanced Budget Act of 1997 (relating to al-
13 ternatives to a single annual dollar cap on outpatient therapy)
14 and under section 221(d) of the Medicare, Medicaid, and
15 SCHIP Balanced Budget Refinement Act of 1999 (relating to
16 utilization patterns for outpatient therapy).

17 (c) IDENTIFICATION OF CONDITIONS AND DISEASES JUS-
18 TIFYING WAIVER OF THERAPY CAP.—

19 (1) STUDY.—The Secretary shall request the Institute
20 of Medicine of the National Academy of Sciences to identify
21 conditions or diseases that should justify conducting an as-
22 sessment of the need to waive the therapy caps under sec-
23 tion 1833(g)(4) of the Social Security Act (42 U.S.C.
24 1395l(g)(4)).

25 (2) REPORTS TO CONGRESS.—

26 (A) PRELIMINARY REPORT.—Not later than July
27 1, 2004, the Secretary shall submit to Congress a pre-
28 liminary report on the conditions and diseases identi-
29 fied under paragraph (1).

30 (B) FINAL REPORT.—Not later than September 1,
31 2004, the Secretary shall submit to Congress a final re-
32 port on such conditions and diseases.

33 (C) RECOMMENDATIONS.—Not later than October
34 1, 2004, the Secretary shall submit to Congress a rec-
35 ommendation of criteria, with respect to such condi-
36 tions and disease, under which a waiver of the therapy
37 caps would apply.



1 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
2 THERAPIST SERVICES.—

3 (1) STUDY.—The Comptroller General of the United
4 States shall conduct a study on access to physical therapist
5 services in States authorizing such services without a physi-
6 cian referral and in States that require such a physician re-
7 ferral. The study shall—

8 (A) examine the use of and referral patterns for
9 physical therapist services for patients age 50 and older
10 in States that authorize such services without a physi-
11 cian referral and in States that require such a physi-
12 cian referral;

13 (B) examine the use of and referral patterns for
14 physical therapist services for patients who are medi-
15 care beneficiaries;

16 (C) examine the potential effect of prohibiting a
17 physician from referring patients to physical therapy
18 services owned by the physician and provided in the
19 physician's office;

20 (D) examine the delivery of physical therapists'
21 services within the facilities of Department of Defense;
22 and

23 (E) analyze the potential impact on medicare
24 beneficiaries and on expenditures under the medicare
25 program of eliminating the need for a physician refer-
26 ral and physician certification for physical therapist
27 services under the medicare program.

28 (2) REPORT.—The Comptroller General shall submit
29 to Congress a report on the study conducted under para-
30 graph (1) by not later than 1 year after the date of the
31 enactment of this Act.

32 **SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES**
33 **FURNISHED IN AMBULATORY SURGICAL**
34 **CENTERS.**

35 Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is
36 amended in the last sentence by inserting “and each of fiscal



1 years 2004 through 2008” after “In each of the fiscal years
2 1998 through 2002”.

3 **SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS**
4 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**
5 **AND PROSTHETICS.**

6 (a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o))
7 is amended—

8 (1) in paragraph (1), by striking “no more than the
9 limits established under paragraph (2)” and inserting “no
10 more than the amount of payment applicable under para-
11 graph (2)”;

12 (2) in paragraph (2), to read as follows:

13 “(2)(A) Except as provided by the Secretary under sub-
14 paragraphs (B) and (C), the amount of payment under this
15 paragraph for custom molded shoes, extra depth shoes, and in-
16 serts shall be the amount determined for such items by the
17 Secretary under section 1834(h).

18 “(B) The Secretary or a carrier may establish payment
19 amounts for shoes and inserts that are lower than the amount
20 established under section 1834(h) if the Secretary finds that
21 shoes and inserts of an appropriate quality are readily available
22 at or below the amount established under such section.

23 “(C) In accordance with procedures established by the
24 Secretary, an individual entitled to benefits with respect to
25 shoes described in section 1861(s)(12) may substitute modifica-
26 tion of such shoes instead of obtaining one (or more, as speci-
27 fied by the Secretary) pair of inserts (other than the original
28 pair of inserts with respect to such shoes). In such case, the
29 Secretary shall substitute, for the payment amount established
30 under section 1834(h), a payment amount that the Secretary
31 estimates will assure that there is no net increase in expendi-
32 tures under this subsection as a result of this subparagraph.”.

33 (b) CONFORMING AMENDMENTS.—(1) Section
34 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by in-
35 sserting “(and includes shoes described in section 1861(s)(12))”
36 after “in section 1861(s)(9)”.



1 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amend-
2 ed by striking subparagraph (C).

3 (c) EFFECTIVE DATE.—The amendments made by this
4 section shall apply to items furnished on or after January 1,
5 2004.

6 **SEC. 627. WAIVER OF PART B LATE ENROLLMENT PEN-**
7 **ALTY FOR CERTAIN MILITARY RETIREES;**
8 **SPECIAL ENROLLMENT PERIOD.**

9 (a) WAIVER OF PENALTY.—

10 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
11 1395r(b)) is amended by adding at the end the following
12 new sentence: “No increase in the premium shall be ef-
13 fected for a month in the case of an individual who is 65
14 years of age or older, who enrolls under this part during
15 2001, 2002, 2003, or 2004 and who demonstrates to the
16 Secretary before December 31, 2004, that the individual is
17 a covered beneficiary (as defined in section 1072(5) of title
18 10, United States Code). The Secretary of Health and
19 Human Services shall consult with the Secretary of De-
20 fense in identifying individuals described in the previous
21 sentence.”.

22 (2) EFFECTIVE DATE.—The amendment made by
23 paragraph (1) shall apply to premiums for months begin-
24 ning with January 2004. The Secretary of Health and
25 Human Services shall establish a method for providing re-
26 bates of premium penalties paid for months on or after
27 January 2004 for which a penalty does not apply under
28 such amendment but for which a penalty was previously
29 collected.

30 (b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

31 (1) IN GENERAL.—In the case of any individual who,
32 as of the date of the enactment of this Act, is 65 years of
33 age or older, is eligible to enroll but is not enrolled under
34 part B of title XVIII of the Social Security Act, and is a
35 covered beneficiary (as defined in section 1072(5) of title
36 10, United States Code), the Secretary of Health and
37 Human Services shall provide for a special enrollment pe-



1 riod during which the individual may enroll under such
2 part. Such period shall begin as soon as possible after the
3 date of the enactment of this Act and shall end on Decem-
4 ber 31, 2004.

5 (2) COVERAGE PERIOD.—In the case of an individual
6 who enrolls during the special enrollment period provided
7 under paragraph (1), the coverage period under part B of
8 title XVIII of the Social Security Act shall begin on the
9 first day of the month following the month in which the in-
10 dividual enrolls.

11 **SEC. 628. EXTENSION OF COVERAGE OF INTRAVENOUS**
12 **IMMUNE GLOBULIN (IVIG) FOR THE TREAT-**
13 **MENT OF PRIMARY IMMUNE DEFICIENCY**
14 **DISEASES IN THE HOME.**

15 (a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as
16 amended by sections 611(a) and 612(a) is amended—

17 (1) in subsection (s)(2)—

18 (A) by striking “and” at the end of subparagraph
19 (W);

20 (B) by adding “and” at the end of subparagraph
21 (X); and

22 (C) by adding at the end the following new sub-
23 paragraph:

24 “(Y) intravenous immune globulin for the treat-
25 ment of primary immune deficiency diseases in the
26 home (as defined in subsection (yy));” and

27 (2) by adding at the end the following new subsection:

28 “**Intravenous Immune Globulin**

29 “(yy) The term ‘intravenous immune globulin’ means an
30 approved pooled plasma derivative for the treatment in the pa-
31 tient’s home of a patient with a diagnosed primary immune de-
32 ficiency disease, but not including items or services related to
33 the administration of the derivative, if a physician determines
34 administration of the derivative in the patient’s home is medi-
35 cally appropriate.”.

36 (b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section
37 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by in-



1 serting “(including intravenous immune globulin (as defined in
2 section 1861(yy)))” after “with respect to drugs and
3 biologicals”.

4 (c) EFFECTIVE DATE.—The amendments made by this
5 section shall apply to items furnished administered on or after
6 January 1, 2004.

7 **SEC. 629. MEDICARE COVERAGE OF DIABETES LABORA-**
8 **TORY DIAGNOSTIC TESTS.**

9 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
10 1395x(s)(2)), as amended by sections 611 and 612, is
11 amended—

12 (1) in subparagraph (W), by striking “and” at the
13 end;

14 (2) in subparagraph (X), by adding “and” at the end;
15 and

16 (3) by adding at the end the following new subpara-
17 graph:

18 “(Y) diabetes screening tests and services (as defined
19 in subsection (yy));”.

20 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
21 1395x), as amended by sections 611 and 612, is further
22 amended by adding at the end the following new subsection:

23 “Diabetes Screening Tests and Services

24 “(yy)(1) The term ‘diabetes screening tests’ means diag-
25 nostic testing furnished to an individual at risk for diabetes (as
26 defined in paragraph (2)) for the purpose of early detection of
27 diabetes, including—

28 “(A) a fasting plasma glucose test; and

29 “(B) such other tests, and modifications to tests, as
30 the Secretary determines appropriate, in consultation with
31 appropriate organizations.

32 “(2) For purposes of paragraph (1), the term ‘individual
33 at risk for diabetes’ means an individual who has any, a com-
34 bination of, or all of the following risk factors for diabetes:

35 “(A) A family history of diabetes.

36 “(B) Overweight defined as a body mass index greater
37 than or equal to 25 kg/m².



- 1 “(C) Habitual physical inactivity.
2 “(D) Belonging to a high-risk ethnic or racial group.
3 “(E) Previous identification of an elevated impaired
4 fasting glucose.
5 “(F) Identification of impaired glucose tolerance.
6 “(G) Hypertension.
7 “(H) Dyslipidemia.
8 “(I) History of gestational diabetes mellitus or delivery
9 of a baby weighing greater than 9 pounds.
10 “(J) Polycystic ovary syndrome.

11 “(3) The Secretary shall establish standards, in consulta-
12 tion with appropriate organizations, regarding the frequency of
13 diabetes screening tests, except that such frequency may not be
14 more often than twice within the 12-month period following the
15 date of the most recent diabetes screening test of that indi-
16 vidual.”.

17 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
18 1395y(a)(1)), as amended by sections 611 and 612, is
19 amended—

20 (1) by striking “and” at the end of subparagraph (J);

21 (2) by striking the semicolon at the end of subpara-
22 graph (K) and inserting “; and”; and

23 (3) by adding at the end the following new subpara-
24 graph:

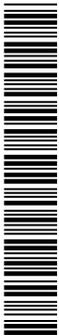
25 “(L) in the case of a diabetes screening tests or serv-
26 ice (as defined in section 1861(yy)(1)), which is performed
27 more frequently than is covered under section
28 1861(yy)(3).”.

29 (d) EFFECTIVE DATE.—The amendments made by this
30 section shall apply to tests furnished on or after the date that
31 is 90 days after the date of enactment of this Act.

32 **TITLE VII—PROVISIONS RELATING**
33 **TO PARTS A AND B**
34 **Subtitle A—Home Health Services**

35 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

36 (a) CHANGE TO CALENDER YEAR UPDATE.—



1 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
2 1395fff(b)(3)) is amended—

3 (A) in paragraph (3)(B)(i)—

4 (i) by striking “each fiscal year (beginning
5 with fiscal year 2002)” and inserting “fiscal year
6 2002 and for fiscal year 2003 and for each subse-
7 quent year (beginning with 2004)”; and

8 (ii) by inserting “or year” after “the fiscal
9 year”;

10 (B) in paragraph (3)(B)(ii)(II), by striking “any
11 subsequent fiscal year” and inserting “2004 and any
12 subsequent year”;

13 (C) in paragraph (3)(B)(iii), by inserting “or
14 year” after “fiscal year” each place it appears;

15 (D) in paragraph (3)(B)(iv)—

16 (i) by inserting “or year” after “fiscal year”
17 each place it appears; and

18 (ii) by inserting “or years” after “fiscal
19 years”; and

20 (E) in paragraph (5), by inserting “or year” after
21 “fiscal year”.

22 (2) TRANSITION RULE.—The standard prospective
23 payment amount (or amounts) under section 1895(b)(3) of
24 the Social Security Act for the calendar quarter beginning
25 on October 1, 2003, shall be such amount (or amounts) for
26 the previous calendar quarter.

27 (b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—
28 Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as
29 amended by subsection (a)(1)(B), is amended—

30 (1) by striking “or” at the end of subclause (I);

31 (2) by redesignating subclause (II) as subclause (III);

32 (3) in subclause (III), as so redesignated, by striking
33 “2004” and inserting “2007”; and

34 (4) by inserting after subclause (I) the following new
35 subclause:



1 “(II) each of 2004, 2005, and 2006 the
2 home health market basket percentage increase
3 minus 0.4 percentage points; or”.

4 **SEC. 702. MEDPAC STUDY ON MEDICARE MARGINS OF**
5 **HOME HEALTH AGENCIES.**

6 (a) STUDY.—The Medicare Payment Advisory Commission
7 shall conduct a study of payment margins of home health agen-
8 cies under the home health prospective payment system under
9 section 1895 of the Social Security Act (42 U.S.C. 1395fff).
10 Such study shall examine whether systematic differences in
11 payment margins are related to differences in case mix (as
12 measured by home health resource groups (HHRGs)) among
13 such agencies. The study shall use the partial or full-year cost
14 reports filed by home health agencies.

15 (b) REPORT.—Not later than 2 years after the date of the
16 enactment of this Act, the Commission shall submit to Con-
17 gress a report on the study under subsection (a).

18 **SEC. 703. DEMONSTRATION PROJECT TO CLARIFY THE**
19 **DEFINITION OF HOMEBOUND.**

20 (a) DEMONSTRATION PROJECT.—Not later than 180 days
21 after the date of the enactment of this Act, the Secretary shall
22 conduct a two-year demonstration project under part B of title
23 XVIII of the Social Security Act under which medicare bene-
24 ficiaries with chronic conditions described in subsection (b) are
25 deemed to be homebound for purposes of receiving home health
26 services under the medicare program.

27 (b) MEDICARE BENEFICIARY DESCRIBED.—For purposes
28 of subsection (a), a medicare beneficiary is eligible to be
29 deemed to be homebound, without regard to the purpose, fre-
30 quency, or duration of absences from the home, if the
31 beneficiary—

32 (1) has been certified by one physician as an indi-
33 vidual who has a permanent and severe condition that will
34 not improve;

35 (2) requires the individual to receive assistance from
36 another individual with at least 3 out of the 5 activities of
37 daily living for the rest of the individual’s life;



1 (3) requires 1 or more home health services to achieve
2 a functional condition that gives the individual the ability
3 to leave home; and

4 (4) requires technological assistance or the assistance
5 of another person to leave the home.

6 (c) DEMONSTRATION PROJECT SITES.—The demonstra-
7 tion project established under this section shall be conducted in
8 3 States selected by the Secretary to represent the Northeast,
9 Midwest, and Western regions of the United States.

10 (d) LIMITATION ON NUMBER OF PARTICIPANTS.—The ag-
11 gregate number of such beneficiaries that may participate in
12 the project may not exceed 15,000.

13 (e) DATA.—The Secretary shall collect such data on the
14 demonstration project with respect to the provision of home
15 health services to medicare beneficiaries that relates to quality
16 of care, patient outcomes, and additional costs, if any, to the
17 medicare program.

18 (f) REPORT TO CONGRESS.—Not later than 1 year after
19 the date of the completion of the demonstration project under
20 this section, the Secretary shall submit to Congress a report on
21 the project using the data collected under subsection (e) and
22 shall include—

23 (1) an examination of whether the provision of home
24 health services to medicare beneficiaries under the
25 project—

26 (A) adversely effects the provision of home health
27 services under the medicare program; or

28 (B) directly causes an unreasonable increase of ex-
29 penditures under the medicare program for the provi-
30 sion of such services that is directly attributable to
31 such clarification;

32 (2) the specific data evidencing the amount of any in-
33 crease in expenditures that is a directly attributable to the
34 demonstration project (expressed both in absolute dollar
35 terms and as a percentage) above expenditures that would
36 otherwise have been incurred for home health services
37 under the medicare program; and



1 (3) specific recommendations to exempt permanently
2 and severely disabled homebound beneficiaries from restric-
3 tions on the length, frequency and purpose of their ab-
4 sences from the home to qualify for home health services
5 without incurring additional unreasonable costs to the
6 medicare program.

7 (g) WAIVER AUTHORITY.—The Secretary shall waive com-
8 pliance with the requirements of title XVIII of the Social Secu-
9 rity Act (42 U.S.C. 1395 et seq.) to such extent and for such
10 period as the Secretary determines is necessary to conduct
11 demonstration projects.

12 (h) CONSTRUCTION.—Nothing in this section shall be con-
13 strued as waiving any applicable civil monetary penalty, crimi-
14 nal penalty, or other remedy available to the Secretary under
15 title XI or title XVIII of the Social Security Act for acts pro-
16 hibited under such titles, including penalties for false certifi-
17 cations for purposes of receipt of items or services under the
18 medicare program.

19 (i) AUTHORIZATION OF APPROPRIATIONS.—Payments for
20 the costs of carrying out the demonstration project under this
21 section shall be made from the Federal Supplementary Insur-
22 ance Trust Fund under section 1841 of such Act (42 U.S.C.
23 1395t).

24 (j) DEFINITIONS.—In this section:

25 (1) MEDICARE BENEFICIARY.—The term “medicare
26 beneficiary” means an individual who is enrolled under part
27 B of title XVIII of the Social Security Act.

28 (2) HOME HEALTH SERVICES.—The term “home
29 health services” has the meaning given such term in section
30 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

31 (3) ACTIVITIES OF DAILY LIVING DEFINED.—The
32 term “activities of daily living” means eating, toileting,
33 transferring, bathing, and dressing.

34 (4) SECRETARY.—The term “Secretary” means the
35 Secretary of Health and Human Services.



1 **Subtitle B—Chronic Care**
2 **Improvement**

3 **SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT**
4 **UNDER TRADITIONAL FEE-FOR-SERVICE.**

5 Title XVIII is amended by inserting after section 1806 the
6 following new section:

7 “CHRONIC CARE IMPROVEMENT

8 “SEC. 1807. (a) IN GENERAL.—

9 “(1) IN GENERAL.—The Secretary shall establish a
10 process for providing chronic care improvement programs
11 in each CCIA region for medicare beneficiaries who are not
12 enrolled under part C and who have certain chronic condi-
13 tions, such as congestive heart failure, diabetes, chronic ob-
14 structive pulmonary disease (COPD), stroke, prostate and
15 colon cancer, hypertension, or other disease as identified by
16 the Secretary as appropriate for chronic care improvement.
17 Such a process shall begin to be implemented no later than
18 1 year after the date of the enactment of this section.

19 “(2) TERMINOLOGY.—For purposes of this section:

20 “(A) CCIA REGION.—The term ‘CCIA region’
21 means a chronic care improvement administrative re-
22 gion delineated under subsection (b)(2).

23 “(B) CHRONIC CARE IMPROVEMENT PROGRAM.—
24 The terms ‘chronic care improvement program’ and
25 ‘program’ means such a program provided by a con-
26 tractor under this section.

27 “(C) CONTRACTOR.—The term ‘contractor’ means
28 an entity with a contract to provide a chronic care im-
29 provement program in a CCIA region under this sec-
30 tion.

31 “(D) INDIVIDUAL PLAN.—The term ‘individual
32 plan’ means a chronic care improvement plan estab-
33 lished under subsection (c)(5) for an individual.

34 “(3) CONSTRUCTION.—Nothing in this section shall be
35 construed as expanding the amount, duration, or scope of
36 benefits under this title.

37 “(b) COMPETITIVE BIDDING PROCESS.—



1 “(1) IN GENERAL.—Under this section the Secretary
2 shall award contracts to qualified entities for chronic care
3 improvement programs for each CCIA region under this
4 section through a competitive bidding process.

5 “(2) PROCESS.—Under such process—

6 “(A) the Secretary shall delineate the United
7 States into multiple chronic care improvement adminis-
8 trative regions; and

9 “(B) the Secretary shall select at least 2 winning
10 bidders in each CCIA region on the basis of the ability
11 of each bidder to carry out a chronic care improvement
12 program in accordance with this section, in order to
13 achieve improved health and financial outcomes.

14 “(3) ELIGIBLE CONTRACTOR.—A contractor may be a
15 disease improvement organization, health insurer, provider
16 organization, a group of physicians, or any other legal enti-
17 ty that the Secretary determines appropriate.

18 “(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

19 “(1) IN GENERAL.—Each contract under this section
20 shall provide for the operation of a chronic care improve-
21 ment program by a contractor in a CCIA region consistent
22 with this subsection.

23 “(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PAR-
24 TICIPANTS.—Each contractor shall have a method for iden-
25 tifying medicare beneficiaries in the region to whom it will
26 offer services under its program. The contractor shall iden-
27 tify such beneficiaries through claims or other data and
28 other means permitted consistent with applicable disclosure
29 provisions.

30 “(3) INITIAL CONTACT BY SECRETARY.—The Sec-
31 retary shall communicate with each beneficiary identified
32 under paragraph (2) as a prospective participant in one or
33 more programs concerning participation in a program.
34 Such communication may be made by the Secretary (or on
35 behalf of the Secretary) and shall include information on
36 the following:



1 “(A) A description of the advantages to the bene-
2 fiary in participating in a program.

3 “(B) Notification that the contractor offering a
4 program may contact the beneficiary directly con-
5 cerning such participation.

6 “(C) Notification that participation in a program
7 is voluntary.

8 “(D) A description of the method for the bene-
9 fiary to select the single program in which the bene-
10 fiary wishes to participate and for declining to partici-
11 pate and a method for obtaining additional information
12 concerning such participation.

13 “(4) PARTICIPATION.—A medicare beneficiary may
14 participate in only one program under this section and may
15 terminate participation at any time in a manner specified
16 by the Secretary.

17 “(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT
18 PLANS.—

19 “(A) IN GENERAL.—For each beneficiary partici-
20 pating in a program of a contractor under this section,
21 the contractor shall develop with the beneficiary an in-
22 dividualized, goal-oriented chronic care improvement
23 plan.

24 “(B) ELEMENTS OF INDIVIDUAL PLAN.—Each in-
25 dividual plan developed under subparagraph (A) shall
26 include a single point of contact to coordinate care and
27 the following, as appropriate:

28 “(i) Self-improvement education for the bene-
29 fiary (such as education for disease management
30 through medical nutrition therapy) and support
31 education for health care providers, primary care-
32 givers, and family members.

33 “(ii) Coordination of health care services, such
34 as application of a prescription drug regimen and
35 home health services.



1 “(iii) Collaboration with physicians and other
2 providers to enhance communication of relevant
3 clinical information.

4 “(iv) The use of monitoring technologies that
5 enable patient guidance through the exchange of
6 pertinent clinical information, such as vital signs,
7 symptomatic information, and health self-assess-
8 ment.

9 “(v) The provision of information about hos-
10 pice care, pain and palliative care, and end-of-life
11 care.

12 “(C) CONTRACTOR RESPONSIBILITIES.—In estab-
13 lishing and carrying out individual plans under a pro-
14 gram, a contractor shall, directly or through
15 subcontractors—

16 “(i) guide participants in managing their
17 health, including all their co-morbidities, and in
18 performing activities as specified under the ele-
19 ments of the plan;

20 “(ii) use decision support tools such as evi-
21 dence-based practice guidelines or other criteria as
22 determined by the Secretary; and

23 “(iii) develop a clinical information database
24 to track and monitor each participant across set-
25 tings and to evaluate outcomes.

26 “(6) ADDITIONAL REQUIREMENTS.—The Secretary
27 may establish additional requirements for programs and
28 contractors under this section.

29 “(7) ACCREDITATION.—The Secretary may provide
30 that programs that are accredited by qualified organiza-
31 tions may be deemed to meet such requirements under this
32 section as the Secretary may specify.

33 “(c) CONTRACT TERMS.—

34 “(1) IN GENERAL.—A contract under this section shall
35 contain such terms and conditions as the Secretary may
36 specify consistent with this section. The Secretary may not
37 enter into a contract with an entity under this section un-



1 less the entity meets such clinical, quality improvement, fi-
2 nancial, and other requirements as the Secretary deems to
3 be appropriate for the population to be served.

4 “(2) USE OF SUBCONTRACTORS PERMITTED.—A con-
5 tractor may carry out a program directly or through con-
6 tracts with subcontractors.

7 “(3) BUDGET NEUTRAL PAYMENT CONDITION.—In en-
8 tering into a contract with an entity under this subsection,
9 the Secretary shall establish payment rates that assure that
10 there will be no net aggregate increase in payments under
11 this title over any period of 3 years or longer, as agreed
12 to by the Secretary. Under this section, the Secretary shall
13 assure that medicare program outlays plus administrative
14 expenses (that would not have been paid under this title
15 without implementation of this section), including con-
16 tractor fees, shall not exceed the expenditures that would
17 have been incurred under this title for a comparable popu-
18 lation in the absence of the program under this section for
19 the 3-year contract period.

20 “(4) AT RISK RELATIONSHIP.—For purposes of sec-
21 tion 1128B(b)(3)(F), a contract under this section shall be
22 treated as a risk-sharing arrangement referred to in such
23 section.

24 “(5) PERFORMANCE STANDARDS.—Payment to con-
25 tractors under this section shall be subject to the contrac-
26 tor’s meeting of clinical and financial performance stand-
27 ards set by the Secretary.

28 “(6) CONTRACTOR OUTCOMES REPORT.—Each con-
29 tractor offering a program shall monitor and report to the
30 Secretary, in a manner specified by the Secretary, the qual-
31 ity of care and efficacy of such program in terms of—

32 “(A) process measures, such as reductions in er-
33 rors of treatment and rehospitalization rates;

34 “(B) beneficiary and provider satisfaction;

35 “(C) health outcomes; and

36 “(D) financial outcomes.



1 “(7) PHASED IN IMPLEMENTATION.—Nothing in this
2 section shall be construed as preventing the Secretary from
3 phasing in the implementation of programs.

4 “(d) BIENNIAL OUTCOMES REPORTS.—The Secretary
5 shall submit to the Congress biannual reports on the implemen-
6 tation of this section. Each such report shall include informa-
7 tion on—

8 “(1) the scope of implementation (in terms of both re-
9 gions and chronic conditions);

10 “(2) program design; and

11 “(3) improvements in health outcomes and financial
12 efficiencies that result from such implementation.

13 “(e) CLINICAL TRIALS.—The Secretary shall conduct ran-
14 domized clinical trials, that compare program participants with
15 medicare beneficiaries who are offered, but decline, to partici-
16 pate, in order to assess the potential of programs to—

17 “(1) reduce costs under this title; and

18 “(2) improve health outcomes under this title.

19 “(f) AUTHORIZATION OF APPROPRIATIONS.—There are
20 authorized to be appropriated to the Secretary, in appropriate
21 part from the Hospital Insurance Trust Fund and the Supple-
22 mentary Medical Insurance Trust Fund, such sums as may be
23 necessary to provide for contracts with chronic care improve-
24 ment programs under this section.

25 “(g) LIMITATION ON FUNDING.—In no case shall the
26 funding under this section exceed \$100,000,000 over a period
27 of 3 years.”.

28 **SEC. 722. CHRONIC CARE IMPROVEMENT UNDER**
29 **MEDICARE+CHOICE PLANS.**

30 “(a) IN GENERAL.—Section 1852 (42 U.S.C. 1395w-22) is
31 amended—

32 (1) by amending subsection (e) to read as follows:

33 “(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT
34 PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFI-
35 CIENTLY SEVERE CHRONIC CONDITIONS.—

36 “(1) IN GENERAL.—Each Medicare+Choice organiza-
37 tion with respect to each Medicare+Choice plan it offers



1 shall have in effect, for enrollees with multiple or suffi-
2 ciently severe chronic conditions, a chronic care improve-
3 ment program that is designed to manage the needs of
4 such enrollees and that meets the requirements of this sub-
5 section.

6 “(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY
7 SEVERE CHRONIC CONDITIONS.—For purposes of this sub-
8 section, the term ‘enrollee with multiple or sufficiently se-
9 vere chronic conditions’ means, with respect to an enrollee
10 in a Medicare+Choice plan of a Medicare+Choice organi-
11 zation, an enrollee in the plan who has one or more chronic
12 conditions, such as congestive heart failure, diabetes,
13 COPD, stroke, prostate and colon cancer, hypertension, or
14 other disease as identified by the organization as appro-
15 priate for chronic care improvement.

16 “(3) GENERAL REQUIREMENTS.—

17 “(A) IN GENERAL.—Each chronic care improve-
18 ment program under this subsection shall be conducted
19 consistent with this subsection.

20 “(B) IDENTIFICATION OF ENROLLEES.—Each
21 such program shall have a method for monitoring and
22 identifying enrollees with multiple or sufficiently severe
23 chronic conditions that meet the organization’s criteria
24 for participation under the program.

25 “(C) DEVELOPMENT OF PLANS.—For an enrollee
26 identified under subparagraph (B) for participation in
27 a program, the program shall develop, with the enroll-
28 ee’s consent, an individualized, goal-oriented chronic
29 care improvement plan for chronic care improvement.

30 “(D) ELEMENTS OF PLANS.—Each chronic care
31 improvement plan developed under subparagraph (C)
32 shall include a single point of contact to coordinate
33 care and the following, as appropriate:

34 “(i) Self-improvement education for the en-
35 rollee (such as education for disease management
36 through medical nutrition therapy) and support



1 education for health care providers, primary care-
2 givers, and family members.

3 “(ii) Coordination of health care services, such
4 as application of a prescription drug regimen and
5 home health services.

6 “(iii) Collaboration with physicians and other
7 providers to enhance communication of relevant
8 clinical information.

9 “(iv) The use of monitoring technologies that
10 enable patient guidance through the exchange of
11 pertinent clinical information, such as vital signs,
12 symptomatic information, and health self-assess-
13 ment.

14 “(v) The provision of information about hos-
15 pice care, pain and palliative care, and end-of-life
16 care.

17 “(E) ORGANIZATION RESPONSIBILITIES.—In es-
18 tablishing and carrying out chronic care improvement
19 plans for participants under this paragraph, a
20 Medicare+Choice organization shall, directly or
21 through subcontractors—

22 “(i) guide participants in managing their
23 health, including all their co-morbidities, and in
24 performing the activities as specified under the ele-
25 ments of the plan;

26 “(ii) use decision support tools such as evi-
27 dence-based practice guidelines or other criteria as
28 determined by the Secretary; and

29 “(iii) develop a clinical information database
30 to track and monitor each participant across set-
31 tings and to evaluate outcomes.

32 “(3) ADDITIONAL REQUIREMENTS.—The Secretary
33 may establish additional requirements for chronic care im-
34 provement programs under this section.

35 “(4) ACCREDITATION.—The Secretary may provide
36 that chronic care improvement programs that are accred-
37 ited by qualified organizations may be deemed to meet such



1 requirements under this subsection as the Secretary may
2 specify.

3 “(5) OUTCOMES REPORT.—Each Medicare+Choice or-
4 ganization with respect to its chronic care improvement
5 program under this subsection shall monitor and report to
6 the Secretary information on the quality of care and effi-
7 cacy of such program as the Secretary may require.”; and

8 (2) by amending subparagraph (I) of subsection (c)(1)
9 to read as follows:

10 “(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A
11 description of the organization’s chronic care improve-
12 ment program under subsection (e).”.

13 (b) EFFECTIVE DATE.—The amendments made by this
14 section shall apply for contract years beginning on or after 1
15 year after the date of the enactment of this Act.

16 **SEC. 723. INSTITUTE OF MEDICINE REPORT.**

17 (a) STUDY.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services shall contract with the Institute of Medi-
20 cine of the National Academy of Sciences to conduct a
21 study of the barriers to effective integrated care improve-
22 ment for medicare beneficiaries with multiple or severe
23 chronic conditions across settings and over time and to
24 submit a report under subsection (b).

25 (2) SPECIFIC ITEMS.—The study shall examine the
26 statutory and regulatory barriers to coordinating care
27 across settings for medicare beneficiaries in transition from
28 one setting to another (such as between hospital, nursing
29 facility, home health, hospice, and home). The study shall
30 specifically identify the following:

31 (A) Clinical, financial, or administrative require-
32 ments in the medicare program that present barriers to
33 effective, seamless transitions across care settings.

34 (B) Policies that impede the establishment of ad-
35 ministrative and clinical information systems to track
36 health status, utilization, cost, and quality data across
37 settings.



1 (C) State-level requirements that may present bar-
2 riers to better care for medicare beneficiaries.

3 (3) CONSULTATION.—The study under this subsection
4 shall be conducted in consultation with experts in the field
5 of chronic care, consumers, and family caregivers, working
6 to integrate care delivery and create more seamless transi-
7 tions across settings and over time.

8 (b) REPORT.—The report under this subsection shall be
9 submitted to the Secretary and Congress not later than 18
10 months after the date of the enactment of this Act.

11 **SEC. 724. MEDPAC REPORT.**

12 (a) EVALUATION.—shall conduct an evaluation that in-
13 cludes a description of the status of the implementation of
14 chronic care improvement programs under section 1807 of the
15 Social Security Act, the quality of health care services provided
16 to individuals in such program, the health status of the partici-
17 pants of such program, and the cost savings attributed to im-
18 plementation of such program.

19 (b) REPORT.—Not later than 2 years after the date of im-
20 plementation of such chronic care improvement programs, the
21 Commission shall submit a report on such evaluation.

22 **Subtitle C—Other Provisions**

23 **SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT AD-**
24 **VISORY COMMISSION (MEDPAC).**

25 (a) EXAMINATION OF BUDGET CONSEQUENCES.—Section
26 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the
27 end the following new paragraph:

28 “(8) EXAMINATION OF BUDGET CONSEQUENCES.—Be-
29 fore making any recommendations, the Commission shall
30 examine the budget consequences of such recommendations,
31 directly or through consultation with appropriate expert en-
32 tities.”.

33 (b) CONSIDERATION OF EFFICIENT PROVISION OF SERV-
34 ICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–
35 6(b)(2)(B)(i)) is amended by inserting “the efficient provision
36 of” after “expenditures for”.

37 (c) APPLICATION OF DISCLOSURE REQUIREMENTS.—



1 (1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C.
2 1395b–6(c)(2)(D)) is amended by adding at the end the
3 following: “Members of the Commission shall be treated as
4 employees of the Congress for purposes of applying title I
5 of the Ethics in Government Act of 1978 (Public Law 95-
6 521).”.

7 (2) EFFECTIVE DATE.—The amendment made by
8 paragraph (1) shall take effect on January 1, 2004.

9 (d) ADDITIONAL REPORTS.—

10 (1) DATA NEEDS AND SOURCES.—The Medicare Pay-
11 ment Advisory Commission shall conduct a study, and sub-
12 mit a report to Congress by not later than June 1, 2004,
13 on the need for current data, and sources of current data
14 available, to determine the solvency and financial cir-
15 cumstances of hospitals and other medicare providers of
16 services. The Commission shall examine data on uncompen-
17 sated care, as well as the share of uncompensated care ac-
18 counted for by the expenses for treating illegal aliens.

19 (2) USE OF TAX-RELATED RETURNS.—Using return
20 information provided under Form 990 of the Internal Rev-
21 enue Service, the Commission shall submit to Congress, by
22 not later than June 1, 2004, a report on the following:

23 (A) Investments, endowments, and fundraising of
24 hospitals participating under the medicare program and
25 related foundations.

26 (B) Access to capital financing for private and for
27 not-for-profit hospitals.

28 **SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL**
29 **ADULT DAY CARE SERVICES.**

30 (a) ESTABLISHMENT.—Subject to the succeeding provi-
31 sions of this section, the Secretary of Health and Human Serv-
32 ices shall establish a demonstration project (in this section re-
33 ferred to as the “demonstration project”) under which the Sec-
34 retary shall, as part of a plan of an episode of care for home
35 health services established for a medicare beneficiary, permit a
36 home health agency, directly or under arrangements with a
37 medical adult day care facility, to provide medical adult day



1 care services as a substitute for a portion of home health serv-
2 ices that would otherwise be provided in the beneficiary's home.

3 (b) PAYMENT.—

4 (1) IN GENERAL.—The amount of payment for an epi-
5 sode of care for home health services, a portion of which
6 consists of substitute medical adult day care services, under
7 the demonstration project shall be made at a rate equal to
8 95 percent of the amount that would otherwise apply for
9 such home health services under section 1895 of the Social
10 Security Act (42 u.s.c. 1395fff). In no case may a home
11 health agency, or a medical adult day care facility under
12 arrangements with a home health agency, separately charge
13 a beneficiary for medical adult day care services furnished
14 under the plan of care.

15 (2) BUDGET NEUTRALITY FOR DEMONSTRATION
16 PROJECT.—Notwithstanding any other provision of law, the
17 Secretary shall provide for an appropriate reduction in the
18 aggregate amount of additional payments made under sec-
19 tion 1895 of the Social Security Act (42 U.S.C. 1395fff)
20 to reflect any increase in amounts expended from the Trust
21 Funds as a result of the demonstration project conducted
22 under this section.

23 (c) DEMONSTRATION PROJECT SITES.—The project estab-
24 lished under this section shall be conducted in not more than
25 5 States selected by the Secretary that license or certify pro-
26 viders of services that furnish medical adult day care services.

27 (d) DURATION.—The Secretary shall conduct the dem-
28 onstration project for a period of 3 years.

29 (e) VOLUNTARY PARTICIPATION.—Participation of medi-
30 care beneficiaries in the demonstration project shall be vol-
31 untary. The total number of such beneficiaries that may par-
32 ticipate in the project at any given time may not exceed
33 15,000.

34 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting
35 home health agencies to participate under the demonstration
36 project, the Secretary shall give preference to those agencies



1 that are currently licensed or certified through common owner-
2 ship and control to furnish medical adult day care services.

3 (g) WAIVER AUTHORITY.—The Secretary may waive such
4 requirements of title XVIII of the Social Security Act as may
5 be necessary for the purposes of carrying out the demonstra-
6 tion project, other than waiving the requirement that an indi-
7 vidual be homebound in order to be eligible for benefits for
8 home health services.

9 (h) EVALUATION AND REPORT.—The Secretary shall con-
10 duct an evaluation of the clinical and cost effectiveness of the
11 demonstration project. Not later 30 months after the com-
12 mencement of the project, the Secretary shall submit to Con-
13 gress a report on the evaluation, and shall include in the report
14 the following:

15 (1) An analysis of the patient outcomes and costs of
16 furnishing care to the medicare beneficiaries participating
17 in the project as compared to such outcomes and costs to
18 beneficiaries receiving only home health services for the
19 same health conditions.

20 (2) Such recommendations regarding the extension,
21 expansion, or termination of the project as the Secretary
22 determines appropriate.

23 (i) DEFINITIONS.—In this section:

24 (1) HOME HEALTH AGENCY.—The term “home health
25 agency” has the meaning given such term in section
26 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

27 (2) MEDICAL ADULT DAY CARE FACILITY.—The term
28 “medical adult day care facility” means a facility that—

29 (A) has been licensed or certified by a State to
30 furnish medical adult day care services in the State for
31 a continuous 2-year period;

32 (B) is engaged in providing skilled nursing serv-
33 ices and other therapeutic services directly or under ar-
34 rangement with a home health agency;

35 (C) meets such standards established by the Sec-
36 retary to assure quality of care and such other require-
37 ments as the Secretary finds necessary in the interest



1 of the health and safety of individuals who are fur-
2 nished services in the facility; and

3 (D) provides medical adult day care services.

4 (3) MEDICAL ADULT DAY CARE SERVICES.—The term
5 “medical adult day care services” means—

6 (A) home health service items and services de-
7 scribed in paragraphs (1) through (7) of section
8 1861(m) furnished in a medical adult day care facility;

9 (B) a program of supervised activities furnished in
10 a group setting in the facility that—

11 (i) meet such criteria as the Secretary deter-
12 mines appropriate; and

13 (ii) is designed to promote physical and mental
14 health of the individuals; and

15 (C) such other services as the Secretary may
16 specify.

17 (4) MEDICARE BENEFICIARY.—The term “medicare
18 beneficiary” means an individual entitled to benefits under
19 part A of this title, enrolled under part B of this title, or
20 both.

21 **SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL**
22 **COVERAGE DETERMINATION PROCESS TO**
23 **RESPOND TO CHANGES IN TECHNOLOGY.**

24 (a) NATIONAL AND LOCAL COVERAGE DETERMINATION
25 PROCESS.—

26 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
27 amended—

28 (A) in the third sentence of subsection (a) by in-
29 serting “consistent with subsection (k)” after “the Sec-
30 retary shall ensure”; and

31 (B) by adding at the end the following new sub-
32 section:

33 “(k) NATIONAL AND LOCAL COVERAGE DETERMINATION
34 PROCESS.—

35 “(1) CRITERIA AND EVIDENCE USED IN MAKING NA-
36 TIONAL COVERAGE DETERMINATIONS.—The Secretary shall
37 make available to the public the criteria the Secretary uses



1 in making national coverage determinations, including how
2 evidence to demonstrate that a procedure or device is rea-
3 sonable and necessary is considered.

4 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR
5 NATIONAL COVERAGE DETERMINATIONS.—In the case of a
6 request for a national coverage determination that—

7 “(A) does not require a technology assessment
8 from an outside entity or deliberation from the Medi-
9 care Coverage Advisory Committee, the decision on the
10 request shall be made not later than 6 months after the
11 date of the request; or

12 “(B) requires such an assessment or deliberation
13 and in which a clinical trial is not requested, the deci-
14 sion on the request shall be made not later than 12
15 months after the date of the request.

16 “(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL
17 COVERAGE DETERMINATIONS.—At the end of the 6-month
18 period that begins on the date a request for a national cov-
19 erage determination is made, the Secretary shall—

20 “(A) make a draft of proposed decision on the re-
21 quest available to the public through the Medicare
22 Internet site of the Department of Health and Human
23 Services or other appropriate means;

24 “(B) provide a 30-day period for public comment
25 on such draft;

26 “(C) make a final decision on the request within
27 60 days of the conclusion of the 30-day period referred
28 to under subparagraph (B);

29 “(D) include in such final decision summaries of
30 the public comments received and responses thereto;

31 “(E) make available to the public the clinical evi-
32 dence and other data used in making such a decision
33 when the decision differs from the recommendations of
34 the Medicare Coverage Advisory Committee; and.

35 “(F) in the case of a decision to grant the cov-
36 erage determination, assign or temporary or permanent



1 code during the 60-day period referred to in subpara-
2 graph (C).

3 “(4) CONSULTATION WITH OUTSIDE EXPERTS IN CER-
4 TAIN NATIONAL COVERAGE DETERMINATIONS.—With re-
5 spect to a request for a national coverage determination for
6 which there is not a review by the Medicare Coverage Advi-
7 sory Committee, the Secretary shall consult with appro-
8 priate outside clinical experts.

9 “(5) LOCAL COVERAGE DETERMINATION PROCESS.—
10 With respect to local coverage determinations made on or
11 after January 1, 2004—

12 “(A) PLAN TO PROMOTE CONSISTENCY OF COV-
13 ERAGE DETERMINATIONS.—The Secretary shall develop
14 a plan to evaluate new local coverage determinations to
15 determine which determinations should be adopted na-
16 tionally and to what extent greater consistency can be
17 achieved among local coverage determinations.

18 “(B) CONSULTATION.—The Secretary shall re-
19 quire the fiscal intermediaries or carriers providing
20 services within the same area to consult on all new
21 local coverage determinations within the area.

22 “(C) DISSEMINATION OF INFORMATION.—The
23 Secretary should serve as a center to disseminate infor-
24 mation on local coverage determinations among fiscal
25 intermediaries and carriers to reduce duplication of ef-
26 fort.

27 “(6) NATIONAL AND LOCAL COVERAGE DETERMINA-
28 TION DEFINED.—For purposes of this subsection, the
29 terms ‘national coverage determination’ and ‘local coverage
30 determination’ have the meaning given such terms in para-
31 graphs (1)(B) and (2)(B), respectively, of section
32 1869(f).”.

33 (2) EFFECTIVE DATE.—The amendments made by
34 paragraph (1) shall apply to national and local coverage de-
35 terminations as of January 1, 2004.

36 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCI-
37 ATED WITH CERTAIN CLINICAL TRIALS.—



1 (1) IN GENERAL.—With respect to the coverage of
2 routine costs of care for beneficiaries participating in a
3 qualifying clinical trial, as set forth on the date of the en-
4 actment of this Act in National Coverage Determination
5 30-1 of the Medicare Coverage Issues Manual, the Sec-
6 retary shall deem clinical trials conducted in accordance
7 with an investigational device exemption approved under
8 section 520(g) of the Federal Food, Drug, and Cosmetic
9 Act (42 U.S.C. 360j(g)) to be automatically qualified for
10 such coverage.

11 (2) RULE OF CONSTRUCTION.—Nothing in this sub-
12 section shall be construed as authorizing or requiring the
13 Secretary to modify the regulations set forth on the date
14 of the enactment of this Act at subpart B of part 405 of
15 title 42, Code of Federal Regulations, or subpart A of part
16 411 of such title, relating to coverage of, and payment for,
17 a medical device that is the subject of an investigational de-
18 vice exemption by the Food and Drug Administration (ex-
19 cept as may be necessary to implement paragraph (1)).

20 (3) EFFECTIVE DATE.—This subsection shall apply to
21 clinical trials begun before, on, or after the date of the en-
22 actment of this Act and to items and services furnished on
23 or after such date.

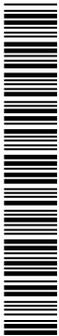
24 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not
25 later than January 1, 2004, the Secretary shall implement re-
26 vised procedures for the issuance of temporary national
27 HCPCS codes under part B of title XVIII of the Social Secu-
28 rity Act.

29 **SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOL-**
30 **OGY SERVICES.**

31 (a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w-
32 4(i)) is amended by adding at the end the following new para-
33 graph:

34 “(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN
35 PATHOLOGY SERVICES.—

36 “(A) IN GENERAL.—With respect to services fur-
37 nished on or after January 1, 2001, and before Janu-



1 ary 1, 2006, if an independent laboratory furnishes the
2 technical component of a physician pathology service to
3 a fee-for-service medicare beneficiary who is an inpa-
4 tient or outpatient of a covered hospital, the Secretary
5 shall treat such component as a service for which pay-
6 ment shall be made to the laboratory under this section
7 and not as an inpatient hospital service for which pay-
8 ment is made to the hospital under section 1886(d) or
9 as a hospital outpatient service for which payment is
10 made to the hospital under section 1833(t).

11 “(B) DEFINITIONS.—In this paragraph:

12 “(i) COVERED HOSPITAL.—

13 “(I) IN GENERAL.—The term ‘covered
14 hospital’ means, with respect to an inpatient or
15 outpatient, a hospital that had an arrangement
16 with an independent laboratory that was in ef-
17 fect as of July 22, 1999, under which a labora-
18 tory furnished the technical component of phy-
19 sician pathology services to fee-for-service
20 medicare beneficiaries who were hospital inpa-
21 tients or outpatients, respectively, and sub-
22 mitted claims for payment for such component
23 to a carrier with a contract under section 1842
24 and not to the hospital.

25 “(II) CHANGE IN OWNERSHIP DOES NOT
26 AFFECT DETERMINATION.—A change in owner-
27 ship with respect to a hospital on or after the
28 date referred to in subclause (I) shall not affect
29 the determination of whether such hospital is a
30 covered hospital for purposes of such subclause.

31 “(ii) FEE-FOR-SERVICE MEDICARE BENE-
32 FICIARY.—The term ‘fee-for-service medicare bene-
33 ficiary’ means an individual who is entitled to bene-
34 fits under part A, or enrolled under this part, or
35 both, but is not enrolled in any of the following:

36 “(I) A Medicare+Choice plan under part
37 C.



1 “(II) A plan offered by an eligible organi-
2 zation under section 1876.

3 “(III) A program of all-inclusive care for
4 the elderly (PACE) under section 1894.

5 “(IV) A social health maintenance organi-
6 zation (SHMO) demonstration project estab-
7 lished under section 4018(b) of the Omnibus
8 Budget Reconciliation Act of 1987 (Public Law
9 100–203).”.

10 (b) CONFORMING AMENDMENT.—Section 542 of the Medi-
11 care, Medicaid, and SCHIP Benefits Improvement and Protec-
12 tion Act of 2000 (114 Stat. 2763A–550), as enacted into law
13 by section 1(a)(6) of Public Law 106–554, is repealed.

14 (c) EFFECTIVE DATES.—The amendments made by this
15 section shall take effect as if included in the enactment of the
16 Medicare, Medicaid, and SCHIP Benefits Improvement and
17 Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463),
18 as enacted into law by section 1(a)(6) of Public Law 106–554.

19 **SEC. 735. MEDICARE PANCREATIC ISLET CELL TRANS-**
20 **PLANT DEMONSTRATION PROJECT.**

21 (a) ESTABLISHMENT.—In order to test the appropriate-
22 ness of pancreatic islet cell transplantation, not later than 120
23 days after the date of the enactment of this Act, the Secretary
24 shall establish a demonstration project which the Secretary,
25 provides for payment under the medicare program under title
26 XVIII of the Social Security Act for pancreatic islet cell trans-
27 plantation and related items and services in the case of medi-
28 care beneficiaries who have type I (juvenile) diabetes and have
29 end stage renal disease.

30 (b) DURATION OF PROJECT.—The authority of the Sec-
31 retary to conduct the demonstration project under this section
32 shall terminate on the date that is 5 years after the date of
33 the establishment of the project.

34 (c) EVALUATION AND REPORT.—The Secretary shall con-
35 duct an evaluation of the outcomes of the demonstration
36 project. Not later than 120 days after the date of the termi-
37 nation of the demonstration project under subsection (b), the



1 Secretary shall submit to Congress a report on the project, in-
2 cluding recommendations for such legislative and administra-
3 tive action as the Secretary deems appropriate.

4 (d) PAYMENT METHODOLOGY.—The Secretary shall estab-
5 lish an appropriate payment methodology for the provision of
6 items and services under the demonstration project, which may
7 include a payment methodology that bundles, to the maximum
8 extent feasible, payment for all such items and services.

9 (e) WAIVER AUTHORITY.—The Secretary may waive com-
10 pliance with the requirements of title XVIII of the Social Secu-
11 rity Act to such extent and for such period as the Secretary
12 determines is necessary to conduct the demonstration project.

13 **TITLE VIII—MEDICAID**

14 **SEC. 801. CONTINUATION OF MEDICAID DSH ALLOT-** 15 **MENT ADJUSTMENTS UNDER BIPA 2000.**

16 (a) IN GENERAL.—Section 1923(f) of the Social Security
17 Act (42 U.S.C. 1396r-4(f))—

18 (1) in paragraph (2)—

19 (A) in the heading, by striking “THROUGH 2002”
20 and inserting “THROUGH 2000”;

21 (B) by striking “ending with fiscal year 2002” and
22 inserting “ending with fiscal year 2000”; and

23 (C) in the table in such paragraph, by striking the
24 columns labeled “FY 01” and “FY02”;

25 (2) in paragraph (3)(A), by striking “paragraph (2)”
26 and inserting “paragraph (4)”; and

27 (3) in paragraph (4), as added by section 701(a)(1) of
28 the Medicare, Medicaid, and SCHIP Benefits Improvement
29 and Protection Act of 2000 (as enacted into law by section
30 1(a)(6) of Public Law 106-554)—

31 (A) by striking “FOR FISCAL YEARS 2001 AND
32 2002” in the heading;

33 (B) in subparagraph (A), by striking “Notwith-
34 standing paragraph (2), the” and inserting “The”;

35 (C) in subparagraph (C)—

36 (i) by striking “NO APPLICATION” and insert-
37 ing “APPLICATION”; and



1 (ii) by striking “without regard to” and insert-
2 ing “taking into account”.

3 (b) INCREASE IN MEDICAID DSH ALLOTMENT FOR THE
4 DISTRICT OF COLUMBIA.—

5 (1) IN GENERAL.—Effective for DSH allotments be-
6 ginning with fiscal year 2003, the item in the table con-
7 tained in section 1923(f)(2) of the Social Security Act (42
8 U.S.C. 1396r-4(f)(2)) for the District of Columbia for the
9 DSH allotment for FY 00 (fiscal year 2000) is amended
10 by striking “32” and inserting “49”.

11 (2) CONSTRUCTION.—Nothing in paragraph (1) shall
12 be construed as preventing the application of section
13 1923(f)(4) of the Social Security Act (as amended by sub-
14 section (a)) to the District of Columbia for fiscal year 2003
15 and subsequent fiscal years.

16 (c) EFFECTIVE DATE.—The amendments made by this
17 section shall apply to DSH allotments for fiscal years beginning
18 with fiscal year 2003.

19 **SEC. 802. INCREASE IN FLOOR FOR TREATMENT AS AN**
20 **EXTREMELY LOW DSH STATE TO 3 PERCENT**
21 **IN FISCAL YEAR 2003.**

22 (a) INCREASE IN DSH FLOOR.—Section 1923(f)(5) of the
23 Social Security Act (42 U.S.C. 1396r-4(f)(5)) is amended—

24 (1) by striking “fiscal year 1999” and inserting “fiscal
25 year 2001”;

26 (2) by striking “August 31, 2000” and inserting “Au-
27 gust 31, 2002”;

28 (3) by striking “1 percent” each place it appears and
29 inserting “3 percent”; and

30 (4) by striking “fiscal year 2001” and inserting “fiscal
31 year 2003”.

32 (b) EFFECTIVE DATE.—The amendments made by sub-
33 section (a) take effect as if enacted on October 1, 2002, and
34 apply to DSH allotments under title XIX of the Social Security
35 Act for fiscal year 2003 and each fiscal year thereafter.



1 **SEC. 803. CLARIFICATION OF INCLUSION OF INPATIENT**
2 **DRUG PRICES CHARGED TO CERTAIN PUB-**
3 **LIC HOSPITALS IN THE BEST PRICE EXEMP-**
4 **TIONS FOR THE MEDICAID DRUG REBATE**
5 **PROGRAM.**

6 (a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C.
7 1396r-8(c)(1)(C)(i)(I)) is amended by inserting before the
8 semicolon the following: “(including inpatient prices charged to
9 hospitals described in section 340B(a)(4)(L) of the Public
10 Health Service Act)”.

11 **TITLE IX—REGULATORY REDUC-**
12 **TION AND CONTRACTING RE-**
13 **FORM**

14 **Subtitle A—Regulatory Reform**

15 **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

16 (a) CONSTRUCTION.—Nothing in this title shall be
17 construed—

18 (1) to compromise or affect existing legal remedies for
19 addressing fraud or abuse, whether it be criminal prosecu-
20 tion, civil enforcement, or administrative remedies, includ-
21 ing under sections 3729 through 3733 of title 31, United
22 States Code (known as the False Claims Act); or

23 (2) to prevent or impede the Department of Health
24 and Human Services in any way from its ongoing efforts
25 to eliminate waste, fraud, and abuse in the medicare pro-
26 gram.

27 Furthermore, the consolidation of medicare administrative con-
28 tracting set forth in this Act does not constitute consolidation
29 of the Federal Hospital Insurance Trust Fund and the Federal
30 Supplementary Medical Insurance Trust Fund or reflect any
31 position on that issue.

32 (b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C.
33 1395x) is amended by inserting after subsection (c) the fol-
34 lowing new subsection:

35 “Supplier

36 “(d) The term ‘supplier’ means, unless the context other-
37 wise requires, a physician or other practitioner, a facility, or



1 other entity (other than a provider of services) that furnishes
2 items or services under this title.”.

3 **SEC. 902. ISSUANCE OF REGULATIONS.**

4 (a) REGULAR TIMELINE FOR PUBLICATION OF FINAL
5 RULES.—

6 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
7 1395hh(a)) is amended by adding at the end the following
8 new paragraph:

9 “(3)(A) The Secretary, in consultation with the Director
10 of the Office of Management and Budget, shall establish and
11 publish a regular timeline for the publication of final regula-
12 tions based on the previous publication of a proposed regulation
13 or an interim final regulation.

14 “(B) Such timeline may vary among different regulations
15 based on differences in the complexity of the regulation, the
16 number and scope of comments received, and other relevant
17 factors, but shall not be longer than 3 years except under ex-
18 ceptional circumstances. If the Secretary intends to vary such
19 timeline with respect to the publication of a final regulation,
20 the Secretary shall cause to have published in the Federal Reg-
21 ister notice of the different timeline by not later than the
22 timeline previously established with respect to such regulation.
23 Such notice shall include a brief explanation of the justification
24 for such variation.

25 “(C) In the case of interim final regulations, upon the ex-
26 piration of the regular timeline established under this para-
27 graph for the publication of a final regulation after opportunity
28 for public comment, the interim final regulation shall not con-
29 tinue in effect unless the Secretary publishes (at the end of the
30 regular timeline and, if applicable, at the end of each suc-
31 ceeding 1-year period) a notice of continuation of the regulation
32 that includes an explanation of why the regular timeline (and
33 any subsequent 1-year extension) was not complied with. If
34 such a notice is published, the regular timeline (or such
35 timeline as previously extended under this paragraph) for publi-
36 cation of the final regulation shall be treated as having been
37 extended for 1 additional year.



1 “(D) The Secretary shall annually submit to Congress a
2 report that describes the instances in which the Secretary failed
3 to publish a final regulation within the applicable regular
4 timeline under this paragraph and that provides an explanation
5 for such failures.”.

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall take effect on the date of the enact-
8 ment of this Act. The Secretary shall provide for an appro-
9 priate transition to take into account the backlog of pre-
10 viously published interim final regulations.

11 (b) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
12 TIONS.—

13 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
14 1395hh(a)), as amended by subsection (a), is amended by
15 adding at the end the following new paragraph:

16 “(4) If the Secretary publishes a final regulation that in-
17 cludes a provision that is not a logical outgrowth of a pre-
18 viously published notice of proposed rulemaking or interim final
19 rule, such provision shall be treated as a proposed regulation
20 and shall not take effect until there is the further opportunity
21 for public comment and a publication of the provision again as
22 a final regulation.”.

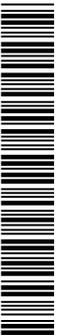
23 (2) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall apply to final regulations published on
25 or after the date of the enactment of this Act.

26 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULA-**
27 **TIONS AND POLICIES.**

28 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE
29 CHANGES.—

30 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh),
31 as amended by section 902(a), is amended by adding at the
32 end the following new subsection:

33 “(e)(1)(A) A substantive change in regulations, manual in-
34 structions, interpretative rules, statements of policy, or guide-
35 lines of general applicability under this title shall not be applied
36 (by extrapolation or otherwise) retroactively to items and serv-



1 ices furnished before the effective date of the change, unless
2 the Secretary determines that—

3 “(i) such retroactive application is necessary to comply
4 with statutory requirements; or

5 “(ii) failure to apply the change retroactively would be
6 contrary to the public interest.”.

7 (2) EFFECTIVE DATE.—The amendment made by
8 paragraph (1) shall apply to substantive changes issued on
9 or after the date of the enactment of this Act.

10 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
11 CHANGES AFTER NOTICE.—

12 (1) IN GENERAL.—Section 1871(e)(1), as added by
13 subsection (a), is amended by adding at the end the fol-
14 lowing:

15 “(B)(i) Except as provided in clause (ii), a substantive
16 change referred to in subparagraph (A) shall not become effec-
17 tive before the end of the 30-day period that begins on the date
18 that the Secretary has issued or published, as the case may be,
19 the substantive change.

20 “(ii) The Secretary may provide for such a substantive
21 change to take effect on a date that precedes the end of the
22 30-day period under clause (i) if the Secretary finds that waiv-
23 er of such 30-day period is necessary to comply with statutory
24 requirements or that the application of such 30-day period is
25 contrary to the public interest. If the Secretary provides for an
26 earlier effective date pursuant to this clause, the Secretary
27 shall include in the issuance or publication of the substantive
28 change a finding described in the first sentence, and a brief
29 statement of the reasons for such finding.

30 “(C) No action shall be taken against a provider of serv-
31 ices or supplier with respect to noncompliance with such a sub-
32 stantive change for items and services furnished before the ef-
33 fective date of such a change.”.

34 (2) EFFECTIVE DATE.—The amendment made by
35 paragraph (1) shall apply to compliance actions undertaken
36 on or after the date of the enactment of this Act.

37 (c) RELIANCE ON GUIDANCE.—



1 (1) IN GENERAL.—Section 1871(e), as added by sub-
2 section (a), is further amended by adding at the end the
3 following new paragraph:

4 “(2)(A) If—

5 “(i) a provider of services or supplier follows the writ-
6 ten guidance (which may be transmitted electronically) pro-
7 vided by the Secretary or by a medicare contractor (as de-
8 fined in section 1889(g)) acting within the scope of the
9 contractor’s contract authority, with respect to the fur-
10 nishing of items or services and submission of a claim for
11 benefits for such items or services with respect to such pro-
12 vider or supplier;

13 “(ii) the Secretary determines that the provider of
14 services or supplier has accurately presented the cir-
15 cumstances relating to such items, services, and claim to
16 the contractor in writing; and

17 “(iii) the guidance was in error;
18 the provider of services or supplier shall not be subject to any
19 sanction (including any penalty or requirement for repayment
20 of any amount) if the provider of services or supplier reason-
21 ably relied on such guidance.

22 “(B) Subparagraph (A) shall not be construed as pre-
23 venting the recoupment or repayment (without any additional
24 penalty) relating to an overpayment insofar as the overpayment
25 was solely the result of a clerical or technical operational
26 error.”.

27 (2) EFFECTIVE DATE.—The amendment made by
28 paragraph (1) shall take effect on the date of the enact-
29 ment of this Act but shall not apply to any sanction for
30 which notice was provided on or before the date of the en-
31 actment of this Act.

32 **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**
33 **LATORY REFORM.**

34 (a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

35 (1) STUDY.—The Comptroller General of the United
36 States shall conduct a study to determine the feasibility
37 and appropriateness of establishing in the Secretary au-



1 thority to provide legally binding advisory opinions on ap-
2 propriate interpretation and application of regulations to
3 carry out the medicare program under title XVIII of the
4 Social Security Act. Such study shall examine the appro-
5 priate timeframe for issuing such advisory opinions, as well
6 as the need for additional staff and funding to provide such
7 opinions.

8 (2) REPORT.—The Comptroller General shall submit
9 to Congress a report on the study conducted under para-
10 graph (1) by not later than one year after the date of the
11 enactment of this Act.

12 (b) REPORT ON LEGAL AND REGULATORY INCONSIST-
13 ENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by
14 section 902(a), is amended by adding at the end the following
15 new subsection:

16 “(f)(1) Not later than 2 years after the date of the enact-
17 ment of this subsection, and every 2 years thereafter, the Sec-
18 retary shall submit to Congress a report with respect to the ad-
19 ministration of this title and areas of inconsistency or conflict
20 among the various provisions under law and regulation.

21 “(2) In preparing a report under paragraph (1), the Sec-
22 retary shall collect—

23 “(A) information from individuals entitled to benefits
24 under part A or enrolled under part B, or both, providers
25 of services, and suppliers and from the Medicare Bene-
26 ficiary Ombudsman and the Medicare Provider Ombuds-
27 man with respect to such areas of inconsistency and con-
28 flict; and

29 “(B) information from medicare contractors that
30 tracks the nature of written and telephone inquiries.

31 “(3) A report under paragraph (1) shall include a descrip-
32 tion of efforts by the Secretary to reduce such inconsistency or
33 conflicts, and recommendations for legislation or administrative
34 action that the Secretary determines appropriate to further re-
35 duce such inconsistency or conflicts.”.



1 **Subtitle B—Contracting Reform**

2 **SEC. 911. INCREASED FLEXIBILITY IN MEDICARE AD-**
3 **MINISTRATION.**

4 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
5 MINISTRATION.—

6 (1) IN GENERAL.—Title XVIII is amended by insert-
7 ing after section 1874 the following new section:

8 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

9 “SEC. 1874A. (a) AUTHORITY.—

10 “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The
11 Secretary may enter into contracts with any eligible entity
12 to serve as a medicare administrative contractor with re-
13 spect to the performance of any or all of the functions de-
14 scribed in paragraph (4) or parts of those functions (or, to
15 the extent provided in a contract, to secure performance
16 thereof by other entities).

17 “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible
18 to enter into a contract with respect to the performance of
19 a particular function described in paragraph (4) only if—

20 “(A) the entity has demonstrated capability to
21 carry out such function;

22 “(B) the entity complies with such conflict of in-
23 terest standards as are generally applicable to Federal
24 acquisition and procurement;

25 “(C) the entity has sufficient assets to financially
26 support the performance of such function; and

27 “(D) the entity meets such other requirements as
28 the Secretary may impose.

29 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR DE-
30 FINED.—For purposes of this title and title XI—

31 “(A) IN GENERAL.—The term ‘medicare adminis-
32 trative contractor’ means an agency, organization, or
33 other person with a contract under this section.

34 “(B) APPROPRIATE MEDICARE ADMINISTRATIVE
35 CONTRACTOR.—With respect to the performance of a
36 particular function in relation to an individual entitled
37 to benefits under part A or enrolled under part B, or



1 both, a specific provider of services or supplier (or class
2 of such providers of services or suppliers), the ‘appro-
3 priate’ medicare administrative contractor is the medi-
4 care administrative contractor that has a contract
5 under this section with respect to the performance of
6 that function in relation to that individual, provider of
7 services or supplier or class of provider of services or
8 supplier.

9 “(4) FUNCTIONS DESCRIBED.—The functions referred
10 to in paragraphs (1) and (2) are payment functions, pro-
11 vider services functions, and functions relating to services
12 furnished to individuals entitled to benefits under part A
13 or enrolled under part B, or both, as follows:

14 “(A) DETERMINATION OF PAYMENT AMOUNTS.—
15 Determining (subject to the provisions of section 1878
16 and to such review by the Secretary as may be provided
17 for by the contracts) the amount of the payments re-
18 quired pursuant to this title to be made to providers of
19 services, suppliers and individuals.

20 “(B) MAKING PAYMENTS.—Making payments de-
21 scribed in subparagraph (A) (including receipt, dis-
22 bursement, and accounting for funds in making such
23 payments).

24 “(C) BENEFICIARY EDUCATION AND ASSIST-
25 ANCE.—Providing education and outreach to individ-
26 uals entitled to benefits under part A or enrolled under
27 part B, or both, and providing assistance to those indi-
28 viduals with specific issues, concerns or problems.

29 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
30 viding consultative services to institutions, agencies,
31 and other persons to enable them to establish and
32 maintain fiscal records necessary for purposes of this
33 title and otherwise to qualify as providers of services or
34 suppliers.

35 “(E) COMMUNICATION WITH PROVIDERS.—Com-
36 municating to providers of services and suppliers any
37 information or instructions furnished to the medicare



1 administrative contractor by the Secretary, and facili-
2 tating communication between such providers and sup-
3 pliers and the Secretary.

4 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
5 SISTANCE.—Performing the functions relating to pro-
6 vider education, training, and technical assistance.

7 “(G) ADDITIONAL FUNCTIONS.—Performing such
8 other functions as are necessary to carry out the pur-
9 poses of this title.

10 “(5) RELATIONSHIP TO MIP CONTRACTS.—

11 “(A) NONDUPLICATION OF DUTIES.—In entering
12 into contracts under this section, the Secretary shall
13 assure that functions of medicare administrative con-
14 tractors in carrying out activities under parts A and B
15 do not duplicate activities carried out under the Medi-
16 care Integrity Program under section 1893. The pre-
17 vious sentence shall not apply with respect to the activ-
18 ity described in section 1893(b)(5) (relating to prior
19 authorization of certain items of durable medical equip-
20 ment under section 1834(a)(15)).

21 “(B) CONSTRUCTION.—An entity shall not be
22 treated as a medicare administrative contractor merely
23 by reason of having entered into a contract with the
24 Secretary under section 1893.

25 “(6) APPLICATION OF FEDERAL ACQUISITION REGULA-
26 TION.—Except to the extent inconsistent with a specific re-
27 quirement of this title, the Federal Acquisition Regulation
28 applies to contracts under this title.

29 “(b) CONTRACTING REQUIREMENTS.—

30 “(1) USE OF COMPETITIVE PROCEDURES.—

31 “(A) IN GENERAL.—Except as provided in laws
32 with general applicability to Federal acquisition and
33 procurement or in subparagraph (B), the Secretary
34 shall use competitive procedures when entering into
35 contracts with medicare administrative contractors
36 under this section, taking into account performance
37 quality as well as price and other factors.



1 “(B) RENEWAL OF CONTRACTS.—The Secretary
2 may renew a contract with a medicare administrative
3 contractor under this section from term to term with-
4 out regard to section 5 of title 41, United States Code,
5 or any other provision of law requiring competition, if
6 the medicare administrative contractor has met or ex-
7 ceeded the performance requirements applicable with
8 respect to the contract and contractor, except that the
9 Secretary shall provide for the application of competi-
10 tive procedures under such a contract not less fre-
11 quently than once every five years.

12 “(C) TRANSFER OF FUNCTIONS.—The Secretary
13 may transfer functions among medicare administrative
14 contractors consistent with the provisions of this para-
15 graph. The Secretary shall ensure that performance
16 quality is considered in such transfers. The Secretary
17 shall provide public notice (whether in the Federal Reg-
18 ister or otherwise) of any such transfer (including a de-
19 scription of the functions so transferred, a description
20 of the providers of services and suppliers affected by
21 such transfer, and contact information for the contrac-
22 tors involved).

23 “(D) INCENTIVES FOR QUALITY.—The Secretary
24 shall provide incentives for medicare administrative
25 contractors to provide quality service and to promote
26 efficiency.

27 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
28 tract under this section shall be entered into with any
29 medicare administrative contractor unless the Secretary
30 finds that such medicare administrative contractor will per-
31 form its obligations under the contract efficiently and effec-
32 tively and will meet such requirements as to financial re-
33 sponsibility, legal authority, quality of services provided,
34 and other matters as the Secretary finds pertinent.

35 “(3) PERFORMANCE REQUIREMENTS.—

36 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE
37 REQUIREMENTS.—In developing contract performance



1 requirements, the Secretary shall develop performance
2 requirements applicable to functions described in sub-
3 section (a)(4).

4 “(B) CONSULTATION.— In developing such re-
5 quirements, the Secretary may consult with providers
6 of services and suppliers, organizations representing in-
7 dividuals entitled to benefits under part A or enrolled
8 under part B, or both, and organizations and agencies
9 performing functions necessary to carry out the pur-
10 poses of this section with respect to such performance
11 requirements.

12 “(C) INCLUSION IN CONTRACTS.—All contractor
13 performance requirements shall be set forth in the con-
14 tract between the Secretary and the appropriate medi-
15 care administrative contractor. Such performance
16 requirements—

17 “(i) shall reflect the performance requirements
18 developed under subparagraph (A), but may in-
19 clude additional performance requirements;

20 “(ii) shall be used for evaluating contractor
21 performance under the contract; and

22 “(iii) shall be consistent with the written state-
23 ment of work provided under the contract.

24 “(4) INFORMATION REQUIREMENTS.—The Secretary
25 shall not enter into a contract with a medicare administra-
26 tive contractor under this section unless the contractor
27 agrees—

28 “(A) to furnish to the Secretary such timely infor-
29 mation and reports as the Secretary may find nec-
30 essary in performing his functions under this title; and

31 “(B) to maintain such records and afford such ac-
32 cess thereto as the Secretary finds necessary to assure
33 the correctness and verification of the information and
34 reports under subparagraph (A) and otherwise to carry
35 out the purposes of this title.

36 “(5) SURETY BOND.—A contract with a medicare ad-
37 ministrative contractor under this section may require the



1 medicare administrative contractor, and any of its officers
2 or employees certifying payments or disbursing funds pur-
3 suant to the contract, or otherwise participating in carrying
4 out the contract, to give surety bond to the United States
5 in such amount as the Secretary may deem appropriate.

6 “(c) TERMS AND CONDITIONS.—

7 “(1) IN GENERAL.—A contract with any medicare ad-
8 ministrative contractor under this section may contain such
9 terms and conditions as the Secretary finds necessary or
10 appropriate and may provide for advances of funds to the
11 medicare administrative contractor for the making of pay-
12 ments by it under subsection (a)(4)(B).

13 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
14 COLLECTION.—The Secretary may not require, as a condi-
15 tion of entering into, or renewing, a contract under this
16 section, that the medicare administrative contractor match
17 data obtained other than in its activities under this title
18 with data used in the administration of this title for pur-
19 poses of identifying situations in which the provisions of
20 section 1862(b) may apply.

21 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-
22 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

23 “(1) CERTIFYING OFFICER.—No individual designated
24 pursuant to a contract under this section as a certifying of-
25 ficer shall, in the absence of the reckless disregard of the
26 individual’s obligations or the intent by that individual to
27 defraud the United States, be liable with respect to any
28 payments certified by the individual under this section.

29 “(2) DISBURSING OFFICER.—No disbursing officer
30 shall, in the absence of the reckless disregard of the offi-
31 cer’s obligations or the intent by that officer to defraud the
32 United States, be liable with respect to any payment by
33 such officer under this section if it was based upon an au-
34 thorization (which meets the applicable requirements for
35 such internal controls established by the Comptroller Gen-
36 eral) of a certifying officer designated as provided in para-
37 graph (1) of this subsection.



1 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-
2 TRACTOR.—

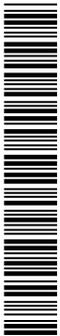
3 “(A) IN GENERAL.—No medicare administrative con-
4 tractor shall be liable to the United States for a payment
5 by a certifying or disbursing officer unless, in connection
6 with such payment, the medicare administrative contractor
7 acted with reckless disregard of its obligations under its
8 medicare administrative contract or with intent to defraud
9 the United States.

10 “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing
11 in this subsection shall be construed to limit liability for
12 conduct that would constitute a violation of sections 3729
13 through 3731 of title 31, United States Code (commonly
14 known as the ‘False Claims Act’).

15 “(4) INDEMNIFICATION BY SECRETARY.—

16 “(A) IN GENERAL.—Subject to subparagraphs (B)
17 and (D), in the case of a medicare administrative con-
18 tractor (or a person who is a director, officer, or em-
19 ployee of such a contractor or who is engaged by the
20 contractor to participate directly in the claims adminis-
21 tration process) who is made a party to any judicial or
22 administrative proceeding arising from or relating di-
23 rectly to the claims administration process under this
24 title, the Secretary may, to the extent the Secretary de-
25 termines to be appropriate and as specified in the con-
26 tract with the contractor, indemnify the contractor and
27 such persons.

28 “(B) CONDITIONS.—The Secretary may not pro-
29 vide indemnification under subparagraph (A) insofar as
30 the liability for such costs arises directly from conduct
31 that is determined by the judicial proceeding or by the
32 Secretary to be criminal in nature, fraudulent, or
33 grossly negligent. If indemnification is provided by the
34 Secretary with respect to a contractor before a deter-
35 mination that such costs arose directly from such con-
36 duct, the contractor shall reimburse the Secretary for
37 costs of indemnification.



1 “(C) SCOPE OF INDEMNIFICATION.—Indemnifica-
2 tion by the Secretary under subparagraph (A) may in-
3 clude payment of judgments, settlements (subject to
4 subparagraph (D)), awards, and costs (including rea-
5 sonable legal expenses).

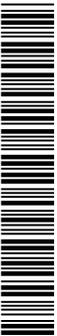
6 “(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A
7 contractor or other person described in subparagraph
8 (A) may not propose to negotiate a settlement or com-
9 promise of a proceeding described in such subpara-
10 graph without the prior written approval of the Sec-
11 retary to negotiate such settlement or compromise. Any
12 indemnification under subparagraph (A) with respect to
13 amounts paid under a settlement or compromise of a
14 proceeding described in such subparagraph are condi-
15 tioned upon prior written approval by the Secretary of
16 the final settlement or compromise.

17 “(E) CONSTRUCTION.—Nothing in this paragraph
18 shall be construed—

19 “(i) to change any common law immunity that
20 may be available to a medicare administrative con-
21 tractor or person described in subparagraph (A); or

22 “(ii) to permit the payment of costs not other-
23 wise allowable, reasonable, or allocable under the
24 Federal Acquisition Regulations.”.

25 (2) CONSIDERATION OF INCORPORATION OF CURRENT
26 LAW STANDARDS.—In developing contract performance re-
27 quirements under section 1874A(b) of the Social Security
28 Act, as inserted by paragraph (1), the Secretary shall con-
29 sider inclusion of the performance standards described in
30 sections 1816(f)(2) of such Act (relating to timely proc-
31 essing of reconsiderations and applications for exemptions)
32 and section 1842(b)(2)(B) of such Act (relating to timely
33 review of determinations and fair hearing requests), as
34 such sections were in effect before the date of the enact-
35 ment of this Act.



1 (b) CONFORMING AMENDMENTS TO SECTION 1816 (RE-
2 LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42
3 U.S.C. 1395h) is amended as follows:

4 (1) The heading is amended to read as follows:
5 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

6 (2) Subsection (a) is amended to read as follows:

7 “(a) The administration of this part shall be conducted
8 through contracts with medicare administrative contractors
9 under section 1874A.”.

10 (3) Subsection (b) is repealed.

11 (4) Subsection (c) is amended—

12 (A) by striking paragraph (1); and

13 (B) in each of paragraphs (2)(A) and (3)(A), by
14 striking “agreement under this section” and inserting
15 “contract under section 1874A that provides for mak-
16 ing payments under this part”.

17 (5) Subsections (d) through (i) are repealed.

18 (6) Subsections (j) and (k) are each amended—

19 (A) by striking “An agreement with an agency or
20 organization under this section” and inserting “A con-
21 tract with a medicare administrative contractor under
22 section 1874A with respect to the administration of
23 this part”; and

24 (B) by striking “such agency or organization” and
25 inserting “such medicare administrative contractor”
26 each place it appears.

27 (7) Subsection (l) is repealed.

28 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-
29 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is
30 amended as follows:

31 (1) The heading is amended to read as follows:
32 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

33 (2) Subsection (a) is amended to read as follows:

34 “(a) The administration of this part shall be conducted
35 through contracts with medicare administrative contractors
36 under section 1874A.”.

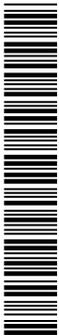
37 (3) Subsection (b) is amended—



- 1 (A) by striking paragraph (1);
- 2 (B) in paragraph (2)—
- 3 (i) by striking subparagraphs (A) and (B);
- 4 (ii) in subparagraph (C), by striking “car-
- 5 riers” and inserting “medicare administrative con-
- 6 tractors”; and
- 7 (iii) by striking subparagraphs (D) and (E);
- 8 (C) in paragraph (3)—
- 9 (i) in the matter before subparagraph (A), by
- 10 striking “Each such contract shall provide that the
- 11 carrier” and inserting “The Secretary”;
- 12 (ii) by striking “will” the first place it appears
- 13 in each of subparagraphs (A), (B), (F), (G), (H),
- 14 and (L) and inserting “shall”;
- 15 (iii) in subparagraph (B), in the matter before
- 16 clause (i), by striking “to the policyholders and
- 17 subscribers of the carrier” and inserting “to the
- 18 policyholders and subscribers of the medicare ad-
- 19 ministrative contractor”;
- 20 (iv) by striking subparagraphs (C), (D), and
- 21 (E);
- 22 (v) in subparagraph (H)—
- 23 (I) by striking “if it makes determinations
- 24 or payments with respect to physicians’ serv-
- 25 ices,” in the matter preceding clause (i); and
- 26 (II) by striking “carrier” and inserting
- 27 “medicare administrative contractor” in clause
- 28 (i);
- 29 (vi) by striking subparagraph (I);
- 30 (vii) in subparagraph (L), by striking the
- 31 semicolon and inserting a period;
- 32 (viii) in the first sentence, after subparagraph
- 33 (L), by striking “and shall contain” and all that
- 34 follows through the period; and
- 35 (ix) in the seventh sentence, by inserting
- 36 “medicare administrative contractor,” after “car-
- 37 rier,”; and



- 1 (D) by striking paragraph (5);
- 2 (E) in paragraph (6)(D)(iv), by striking “carrier”
- 3 and inserting “medicare administrative contractor”;
- 4 and
- 5 (F) in paragraph (7), by striking “the carrier”
- 6 and inserting “the Secretary” each place it appears.
- 7 (4) Subsection (c) is amended—
- 8 (A) by striking paragraph (1);
- 9 (B) in paragraph (2)(A), by striking “contract
- 10 under this section which provides for the disbursement
- 11 of funds, as described in subsection (a)(1)(B),” and in-
- 12 serting “contract under section 1874A that provides for
- 13 making payments under this part”;
- 14 (C) in paragraph (3)(A), by striking “subsection
- 15 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;
- 16 (D) in paragraph (4), in the matter preceding sub-
- 17 paragraph (A), by striking “carrier” and inserting
- 18 “medicare administrative contractor”; and
- 19 (E) by striking paragraphs (5) and (6).
- 20 (5) Subsections (d), (e), and (f) are repealed.
- 21 (6) Subsection (g) is amended by striking “carrier or
- 22 carriers” and inserting “medicare administrative contractor
- 23 or contractors”.
- 24 (7) Subsection (h) is amended—
- 25 (A) in paragraph (2)—
- 26 (i) by striking “Each carrier having an agree-
- 27 ment with the Secretary under subsection (a)” and
- 28 inserting “The Secretary”; and
- 29 (ii) by striking “Each such carrier” and in-
- 30 serting “The Secretary”;
- 31 (B) in paragraph (3)(A)—
- 32 (i) by striking “a carrier having an agreement
- 33 with the Secretary under subsection (a)” and in-
- 34 serting “medicare administrative contractor having
- 35 a contract under section 1874A that provides for
- 36 making payments under this part”; and



1 (ii) by striking “such carrier” and inserting
2 “such contractor”;

3 (C) in paragraph (3)(B)—

4 (i) by striking “a carrier” and inserting “a
5 medicare administrative contractor” each place it
6 appears; and

7 (ii) by striking “the carrier” and inserting
8 “the contractor” each place it appears; and

9 (D) in paragraphs (5)(A) and (5)(B)(iii), by strik-
10 ing “carriers” and inserting “medicare administrative
11 contractors” each place it appears.

12 (8) Subsection (l) is amended—

13 (A) in paragraph (1)(A)(iii), by striking “carrier”
14 and inserting “medicare administrative contractor”;
15 and

16 (B) in paragraph (2), by striking “carrier” and in-
17 serting “medicare administrative contractor”.

18 (9) Subsection (p)(3)(A) is amended by striking “car-
19 rier” and inserting “medicare administrative contractor”.

20 (10) Subsection (q)(1)(A) is amended by striking “car-
21 rier”.

22 (d) EFFECTIVE DATE; TRANSITION RULE.—

23 (1) EFFECTIVE DATE.—

24 (A) IN GENERAL.—Except as otherwise provided
25 in this subsection, the amendments made by this sec-
26 tion shall take effect on October 1, 2005, and the Sec-
27 retary is authorized to take such steps before such date
28 as may be necessary to implement such amendments on
29 a timely basis.

30 (B) CONSTRUCTION FOR CURRENT CONTRACTS.—

31 Such amendments shall not apply to contracts in effect
32 before the date specified under subparagraph (A) that
33 continue to retain the terms and conditions in effect on
34 such date (except as otherwise provided under this Act,
35 other than under this section) until such date as the
36 contract is let out for competitive bidding under such
37 amendments.



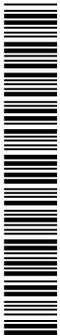
1 (C) DEADLINE FOR COMPETITIVE BIDDING.—The
2 Secretary shall provide for the letting by competitive
3 bidding of all contracts for functions of medicare ad-
4 ministrative contractors for annual contract periods
5 that begin on or after October 1, 2010.

6 (D) WAIVER OF PROVIDER NOMINATION PROVI-
7 SIONS DURING TRANSITION.—During the period begin-
8 ning on the date of the enactment of this Act and be-
9 fore the date specified under subparagraph (A), the
10 Secretary may enter into new agreements under section
11 1816 of the Social Security Act (42 U.S.C. 1395h)
12 without regard to any of the provider nomination provi-
13 sions of such section.

14 (2) GENERAL TRANSITION RULES.—The Secretary
15 shall take such steps, consistent with paragraph (1)(B) and
16 (1)(C), as are necessary to provide for an appropriate tran-
17 sition from contracts under section 1816 and section 1842
18 of the Social Security Act (42 U.S.C. 1395h, 1395u) to
19 contracts under section 1874A, as added by subsection
20 (a)(1).

21 (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS
22 UNDER CURRENT CONTRACTS AND AGREEMENTS AND
23 UNDER ROLLOVER CONTRACTS.—The provisions contained
24 in the exception in section 1893(d)(2) of the Social Secu-
25 rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply
26 notwithstanding the amendments made by this section, and
27 any reference in such provisions to an agreement or con-
28 tract shall be deemed to include a contract under section
29 1874A of such Act, as inserted by subsection (a)(1), that
30 continues the activities referred to in such provisions.

31 (e) REFERENCES.—On and after the effective date pro-
32 vided under subsection (d)(1), any reference to a fiscal inter-
33 mediary or carrier under title XI or XVIII of the Social Secu-
34 rity Act (or any regulation, manual instruction, interpretative
35 rule, statement of policy, or guideline issued to carry out such
36 titles) shall be deemed a reference to a medicare administrative



1 contractor (as provided under section 1874A of the Social Se-
2 curity Act).

3 (f) REPORTS ON IMPLEMENTATION.—

4 (1) PLAN FOR IMPLEMENTATION.—By not later than
5 October 1, 2004, the Secretary shall submit a report to
6 Congress and the Comptroller General of the United States
7 that describes the plan for implementation of the amend-
8 ments made by this section. The Comptroller General shall
9 conduct an evaluation of such plan and shall submit to
10 Congress, not later than 6 months after the date the report
11 is received, a report on such evaluation and shall include
12 in such report such recommendations as the Comptroller
13 General deems appropriate.

14 (2) STATUS OF IMPLEMENTATION.—The Secretary
15 shall submit a report to Congress not later than October
16 1, 2008, that describes the status of implementation of
17 such amendments and that includes a description of the
18 following:

19 (A) The number of contracts that have been com-
20 petitively bid as of such date.

21 (B) The distribution of functions among contracts
22 and contractors.

23 (C) A timeline for complete transition to full com-
24 petition.

25 (D) A detailed description of how the Secretary
26 has modified oversight and management of medicare
27 contractors to adapt to full competition.

28 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**
29 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**
30 **TORS.**

31 (a) IN GENERAL.—Section 1874A, as added by section
32 911(a)(1), is amended by adding at the end the following new
33 subsection:

34 “(e) REQUIREMENTS FOR INFORMATION SECURITY.—

35 “(1) DEVELOPMENT OF INFORMATION SECURITY PRO-
36 GRAM.—A medicare administrative contractor that per-
37 forms the functions referred to in subparagraphs (A) and



1 (B) of subsection (a)(4) (relating to determining and mak-
2 ing payments) shall implement a contractor-wide informa-
3 tion security program to provide information security for
4 the operation and assets of the contractor with respect to
5 such functions under this title. An information security
6 program under this paragraph shall meet the requirements
7 for information security programs imposed on Federal
8 agencies under paragraphs (1) through (8) of section
9 3544(b) of title 44, United States Code (other than the re-
10 quirements under paragraphs (2)(D)(i), (5)(A), and (5)(B)
11 of such section).

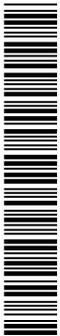
12 “(2) INDEPENDENT AUDITS.—

13 “(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

14 Each year a medicare administrative contractor that
15 performs the functions referred to in subparagraphs
16 (A) and (B) of subsection (a)(4) (relating to deter-
17 mining and making payments) shall undergo an evalua-
18 tion of the information security of the contractor with
19 respect to such functions under this title. The evalua-
20 tion shall—

21 “(i) be performed by an entity that meets such
22 requirements for independence as the Inspector
23 General of the Department of Health and Human
24 Services may establish; and

25 “(ii) test the effectiveness of information secu-
26 rity control techniques of an appropriate subset of
27 the contractor’s information systems (as defined in
28 section 3502(8) of title 44, United States Code) re-
29 lating to such functions under this title and an as-
30 sessment of compliance with the requirements of
31 this subsection and related information security
32 policies, procedures, standards and guidelines, in-
33 cluding policies and procedures as may be pre-
34 scribed by the Director of the Office of Manage-
35 ment and Budget and applicable information secu-
36 rity standards promulgated under section 11331 of
37 title 40, United States Code.



1 “(B) DEADLINE FOR INITIAL EVALUATION.—

2 “(i) NEW CONTRACTORS.—In the case of a
3 medicare administrative contractor covered by this
4 subsection that has not previously performed the
5 functions referred to in subparagraphs (A) and (B)
6 of subsection (a)(4) (relating to determining and
7 making payments) as a fiscal intermediary or car-
8 rier under section 1816 or 1842, the first inde-
9 pendent evaluation conducted pursuant subpara-
10 graph (A) shall be completed prior to commencing
11 such functions.

12 “(ii) OTHER CONTRACTORS.—In the case of a
13 medicare administrative contractor covered by this
14 subsection that is not described in clause (i), the
15 first independent evaluation conducted pursuant
16 subparagraph (A) shall be completed within 1 year
17 after the date the contractor commences functions
18 referred to in clause (i) under this section.

19 “(C) REPORTS ON EVALUATIONS.—

20 “(i) TO THE DEPARTMENT OF HEALTH AND
21 HUMAN SERVICES.—The results of independent
22 evaluations under subparagraph (A) shall be sub-
23 mitted promptly to the Inspector General of the
24 Department of Health and Human Services and to
25 the Secretary.

26 “(ii) TO CONGRESS.—The Inspector General
27 of Department of Health and Human Services shall
28 submit to Congress annual reports on the results of
29 such evaluations, including assessments of the
30 scope and sufficiency of such evaluations.

31 “(iii) AGENCY REPORTING.—The Secretary
32 shall address the results of such evaluations in re-
33 ports required under section 3544(c) of title 44,
34 United States Code.”.

35 (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-
36 MEDIARIES AND CARRIERS.—



1 (1) IN GENERAL.—The provisions of section
2 1874A(e)(2) of the Social Security Act (other than sub-
3 paragraph (B)), as added by subsection (a), shall apply to
4 each fiscal intermediary under section 1816 of the Social
5 Security Act (42 U.S.C. 1395h) and each carrier under
6 section 1842 of such Act (42 U.S.C. 1395u) in the same
7 manner as they apply to medicare administrative contrac-
8 tors under such provisions.

9 (2) DEADLINE FOR INITIAL EVALUATION.—In the case
10 of such a fiscal intermediary or carrier with an agreement
11 or contract under such respective section in effect as of the
12 date of the enactment of this Act, the first evaluation
13 under section 1874A(e)(2)(A) of the Social Security Act
14 (as added by subsection (a)), pursuant to paragraph (1),
15 shall be completed (and a report on the evaluation sub-
16 mitted to the Secretary) by not later than 1 year after such
17 date.

18 **Subtitle C—Education and Outreach**

19 **SEC. 921. PROVIDER EDUCATION AND TECHNICAL AS-** 20 **SISTANCE.**

21 (a) COORDINATION OF EDUCATION FUNDING.—

22 (1) IN GENERAL.—Title XVIII is amended by insert-
23 ing after section 1888 the following new section:

24 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

25 “SEC. 1889. (a) COORDINATION OF EDUCATION FUND-
26 ING.—The Secretary shall coordinate the educational activities
27 provided through medicare contractors (as defined in sub-
28 section (g), including under section 1893) in order to maximize
29 the effectiveness of Federal education efforts for providers of
30 services and suppliers.”.

31 (2) EFFECTIVE DATE.—The amendment made by
32 paragraph (1) shall take effect on the date of the enact-
33 ment of this Act.

34 (3) REPORT.—Not later than October 1, 2004, the
35 Secretary shall submit to Congress a report that includes
36 a description and evaluation of the steps taken to coordi-
37 nate the funding of provider education under section



1 1889(a) of the Social Security Act, as added by paragraph
2 (1).

3 (b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
4 ANCE.—

5 (1) IN GENERAL.—Section 1874A, as added by section
6 911(a)(1) and as amended by section 912(a), is amended
7 by adding at the end the following new subsection:

8 “(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
9 ANCE IN PROVIDER EDUCATION AND OUTREACH.—The Sec-
10 retary shall use specific claims payment error rates or similar
11 methodology of medicare administrative contractors in the
12 processing or reviewing of medicare claims in order to give such
13 contractors an incentive to implement effective education and
14 outreach programs for providers of services and suppliers.”.

15 (2) APPLICATION TO FISCAL INTERMEDIARIES AND
16 CARRIERS.—The provisions of section 1874A(f) of the So-
17 cial Security Act, as added by paragraph (1), shall apply
18 to each fiscal intermediary under section 1816 of the Social
19 Security Act (42 U.S.C. 1395h) and each carrier under
20 section 1842 of such Act (42 U.S.C. 1395u) in the same
21 manner as they apply to medicare administrative contrac-
22 tors under such provisions.

23 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—
24 Not later than October 1, 2004, the Comptroller General
25 of the United States shall submit to Congress and to the
26 Secretary a report on the adequacy of the methodology
27 under section 1874A(f) of the Social Security Act, as added
28 by paragraph (1), and shall include in the report such rec-
29 ommendations as the Comptroller General determines ap-
30 propriate with respect to the methodology.

31 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING
32 CONTRACTOR PERFORMANCE.—Not later than October 1,
33 2004, the Secretary shall submit to Congress a report that
34 describes how the Secretary intends to use such method-
35 ology in assessing medicare contractor performance in im-
36 plementing effective education and outreach programs, in-
37 cluding whether to use such methodology as a basis for per-



1 formance bonuses. The report shall include an analysis of
2 the sources of identified errors and potential changes in
3 systems of contractors and rules of the Secretary that could
4 reduce claims error rates.

5 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES
6 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

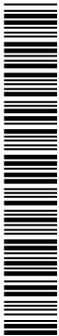
7 (1) IN GENERAL.—Section 1874A, as added by section
8 911(a)(1) and as amended by section 912(a) and sub-
9 section (b), is further amended by adding at the end the
10 following new subsection:

11 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS
12 OF SERVICES AND SUPPLIERS.—

13 “(1) COMMUNICATION STRATEGY.—The Secretary
14 shall develop a strategy for communications with individ-
15 uals entitled to benefits under part A or enrolled under
16 part B, or both, and with providers of services and sup-
17 pliers under this title.

18 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-
19 care administrative contractor shall, for those providers of
20 services and suppliers which submit claims to the con-
21 tractor for claims processing and for those individuals enti-
22 tled to benefits under part A or enrolled under part B, or
23 both, with respect to whom claims are submitted for claims
24 processing, provide general written responses (which may
25 be through electronic transmission) in a clear, concise, and
26 accurate manner to inquiries of providers of services, sup-
27 pliers and individuals entitled to benefits under part A or
28 enrolled under part B, or both, concerning the programs
29 under this title within 45 business days of the date of re-
30 ceipt of such inquiries.

31 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary
32 shall ensure that each medicare administrative contractor
33 shall provide, for those providers of services and suppliers
34 which submit claims to the contractor for claims processing
35 and for those individuals entitled to benefits under part A
36 or enrolled under part B, or both, with respect to whom
37 claims are submitted for claims processing, a toll-free tele-



1 phone number at which such individuals, providers of serv-
2 ices and suppliers may obtain information regarding billing,
3 coding, claims, coverage, and other appropriate information
4 under this title.

5 “(4) MONITORING OF CONTRACTOR RESPONSES.—

6 “(A) IN GENERAL.—Each medicare administrative
7 contractor shall, consistent with standards developed by
8 the Secretary under subparagraph (B)—

9 “(i) maintain a system for identifying who
10 provides the information referred to in paragraphs
11 (2) and (3); and

12 “(ii) monitor the accuracy, consistency, and
13 timeliness of the information so provided.

14 “(B) DEVELOPMENT OF STANDARDS.—

15 “(i) IN GENERAL.—The Secretary shall estab-
16 lish and make public standards to monitor the ac-
17 curacy, consistency, and timeliness of the informa-
18 tion provided in response to written and telephone
19 inquiries under this subsection. Such standards
20 shall be consistent with the performance require-
21 ments established under subsection (b)(3).

22 “(ii) EVALUATION.—In conducting evaluations
23 of individual medicare administrative contractors,
24 the Secretary shall take into account the results of
25 the monitoring conducted under subparagraph (A)
26 taking into account as performance requirements
27 the standards established under clause (i). The
28 Secretary shall, in consultation with organizations
29 representing providers of services, suppliers, and
30 individuals entitled to benefits under part A or en-
31 rolled under part B, or both, establish standards
32 relating to the accuracy, consistency, and timeliness
33 of the information so provided.

34 “(C) DIRECT MONITORING.—Nothing in this para-
35 graph shall be construed as preventing the Secretary
36 from directly monitoring the accuracy, consistency, and
37 timeliness of the information so provided.”



1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall take effect October 1, 2004.

3 (3) APPLICATION TO FISCAL INTERMEDIARIES AND
4 CARRIERS.—The provisions of section 1874A(g) of the So-
5 cial Security Act, as added by paragraph (1), shall apply
6 to each fiscal intermediary under section 1816 of the Social
7 Security Act (42 U.S.C. 1395h) and each carrier under
8 section 1842 of such Act (42 U.S.C. 1395u) in the same
9 manner as they apply to medicare administrative contrac-
10 tors under such provisions.

11 (d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

12 (1) IN GENERAL.—Section 1889, as added by sub-
13 section (a), is amended by adding at the end the following
14 new subsections:

15 “(b) ENHANCED EDUCATION AND TRAINING.—

16 “(1) ADDITIONAL RESOURCES.—There are authorized
17 to be appropriated to the Secretary (in appropriate part
18 from the Federal Hospital Insurance Trust Fund and the
19 Federal Supplementary Medical Insurance Trust Fund)
20 \$25,000,000 for each of fiscal years 2005 and 2006 and
21 such sums as may be necessary for succeeding fiscal years.

22 “(2) USE.—The funds made available under para-
23 graph (1) shall be used to increase the conduct by medicare
24 contractors of education and training of providers of serv-
25 ices and suppliers regarding billing, coding, and other ap-
26 propriate items and may also be used to improve the accu-
27 racy, consistency, and timeliness of contractor responses.

28 “(c) TAILORING EDUCATION AND TRAINING ACTIVITIES
29 FOR SMALL PROVIDERS OR SUPPLIERS.—

30 “(1) IN GENERAL.—Insofar as a medicare contractor
31 conducts education and training activities, it shall tailor
32 such activities to meet the special needs of small providers
33 of services or suppliers (as defined in paragraph (2)).

34 “(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—
35 In this subsection, the term ‘small provider of services or
36 supplier’ means—



1 “(A) a provider of services with fewer than 25 full-
2 time-equivalent employees; or

3 “(B) a supplier with fewer than 10 full-time-equiv-
4 alent employees.”.

5 (2) EFFECTIVE DATE.—The amendment made by
6 paragraph (1) shall take effect on October 1, 2004.

7 (e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

8 (1) IN GENERAL.—Section 1889, as added by sub-
9 section (a) and as amended by subsection (d), is further
10 amended by adding at the end the following new sub-
11 section:

12 “(d) INTERNET SITES; FAQs.—The Secretary, and each
13 medicare contractor insofar as it provides services (including
14 claims processing) for providers of services or suppliers, shall
15 maintain an Internet site which—

16 “(1) provides answers in an easily accessible format to
17 frequently asked questions, and

18 “(2) includes other published materials of the con-
19 tractor,

20 that relate to providers of services and suppliers under the pro-
21 grams under this title (and title XI insofar as it relates to such
22 programs).”.

23 (2) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall take effect on October 1, 2004.

25 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

26 (1) IN GENERAL.—Section 1889, as added by sub-
27 section (a) and as amended by subsections (d) and (e), is
28 further amended by adding at the end the following new
29 subsections:

30 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
31 PROGRAM ACTIVITIES.—A medicare contractor may not use a
32 record of attendance at (or failure to attend) educational activi-
33 ties or other information gathered during an educational pro-
34 gram conducted under this section or otherwise by the Sec-
35 retary to select or track providers of services or suppliers for
36 the purpose of conducting any type of audit or prepayment re-
37 view.



1 “(f) CONSTRUCTION.—Nothing in this section or section
2 1893(g) shall be construed as providing for disclosure by a
3 medicare contractor of information that would compromise
4 pending law enforcement activities or reveal findings of law en-
5 forcement-related audits.

6 “(g) DEFINITIONS.—For purposes of this section, the
7 term ‘medicare contractor’ includes the following:

8 “(1) A medicare administrative contractor with a con-
9 tract under section 1874A, including a fiscal intermediary
10 with a contract under section 1816 and a carrier with a
11 contract under section 1842.

12 “(2) An eligible entity with a contract under section
13 1893.

14 Such term does not include, with respect to activities of a spe-
15 cific provider of services or supplier an entity that has no au-
16 thority under this title or title IX with respect to such activities
17 and such provider of services or supplier.”.

18 “(2) EFFECTIVE DATE.—The amendment made by
19 paragraph (1) shall take effect on the date of the enact-
20 ment of this Act.

21 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE**
22 **DEMONSTRATION PROGRAM.**

23 (a) ESTABLISHMENT.—

24 “(1) IN GENERAL.—The Secretary shall establish a
25 demonstration program (in this section referred to as the
26 “demonstration program”) under which technical assist-
27 ance described in paragraph (2) is made available, upon re-
28 quest and on a voluntary basis, to small providers of serv-
29 ices or suppliers in order to improve compliance with the
30 applicable requirements of the programs under medicare
31 program under title XVIII of the Social Security Act (in-
32 cluding provisions of title XI of such Act insofar as they
33 relate to such title and are not administered by the Office
34 of the Inspector General of the Department of Health and
35 Human Services).

36 “(2) FORMS OF TECHNICAL ASSISTANCE.—The tech-
37 nical assistance described in this paragraph is—



1 (A) evaluation and recommendations regarding
2 billing and related systems; and

3 (B) information and assistance regarding policies
4 and procedures under the medicare program, including
5 coding and reimbursement.

6 (3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—
7 In this section, the term “small providers of services or
8 suppliers” means—

9 (A) a provider of services with fewer than 25 full-
10 time-equivalent employees; or

11 (B) a supplier with fewer than 10 full-time-equiva-
12 lent employees.

13 (b) QUALIFICATION OF CONTRACTORS.—In conducting the
14 demonstration program, the Secretary shall enter into contracts
15 with qualified organizations (such as peer review organizations
16 or entities described in section 1889(g)(2) of the Social Secu-
17 rity Act, as inserted by section 5(f)(1)) with appropriate exper-
18 tise with billing systems of the full range of providers of serv-
19 ices and suppliers to provide the technical assistance. In award-
20 ing such contracts, the Secretary shall consider any prior inves-
21 tigation of the entity’s work by the Inspector General of De-
22 partment of Health and Human Services or the Comptroller
23 General of the United States.

24 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-
25 nical assistance provided under the demonstration program
26 shall include a direct and in-person examination of billing sys-
27 tems and internal controls of small providers of services or sup-
28 pliers to determine program compliance and to suggest more
29 efficient or effective means of achieving such compliance.

30 (d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS
31 IDENTIFIED AS CORRECTED.—The Secretary shall provide
32 that, absent evidence of fraud and notwithstanding any other
33 provision of law, any errors found in a compliance review for
34 a small provider of services or supplier that participates in the
35 demonstration program shall not be subject to recovery action
36 if the technical assistance personnel under the program deter-
37 mine that—



1 (1) the problem that is the subject of the compliance
2 review has been corrected to their satisfaction within 30
3 days of the date of the visit by such personnel to the small
4 provider of services or supplier; and

5 (2) such problem remains corrected for such period as
6 is appropriate.

7 The previous sentence applies only to claims filed as part of the
8 demonstration program and lasts only for the duration of such
9 program and only as long as the small provider of services or
10 supplier is a participant in such program.

11 (e) GAO EVALUATION.—Not later than 2 years after the
12 date of the date the demonstration program is first imple-
13 mented, the Comptroller General, in consultation with the In-
14 spector General of the Department of Health and Human Serv-
15 ices, shall conduct an evaluation of the demonstration program.
16 The evaluation shall include a determination of whether claims
17 error rates are reduced for small providers of services or sup-
18 pliers who participated in the program and the extent of im-
19 proper payments made as a result of the demonstration pro-
20 gram. The Comptroller General shall submit a report to the
21 Secretary and the Congress on such evaluation and shall in-
22 clude in such report recommendations regarding the continu-
23 ation or extension of the demonstration program.

24 (f) FINANCIAL PARTICIPATION BY PROVIDERS.—The pro-
25 vision of technical assistance to a small provider of services or
26 supplier under the demonstration program is conditioned upon
27 the small provider of services or supplier paying an amount es-
28 timated (and disclosed in advance of a provider's or supplier's
29 participation in the program) to be equal to 25 percent of the
30 cost of the technical assistance.

31 (g) AUTHORIZATION OF APPROPRIATIONS.—There are au-
32 thorized to be appropriated to the Secretary (in appropriate
33 part from the Federal Hospital Insurance Trust Fund and the
34 Federal Supplementary Medical Insurance Trust Fund) to
35 carry out the demonstration program—

36 (1) for fiscal year 2005, \$1,000,000, and

37 (2) for fiscal year 2006, \$6,000,000.



1 **SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDI-**
2 **CARE BENEFICIARY OMBUDSMAN.**

3 (a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868
4 (42 U.S.C. 1395ee) is amended—

5 (1) by adding at the end of the heading the following:
6 “; MEDICARE PROVIDER OMBUDSMAN”;

7 (2) by inserting “PRACTICING PHYSICIANS ADVISORY
8 COUNCIL.—(1)” after “(a)”;

9 (3) in paragraph (1), as so redesignated under para-
10 graph (2), by striking “in this section” and inserting “in
11 this subsection”;

12 (4) by redesignating subsections (b) and (c) as para-
13 graphs (2) and (3), respectively; and

14 (5) by adding at the end the following new subsection:
15 “(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary
16 shall appoint within the Department of Health and Human
17 Services a Medicare Provider Ombudsman. The Ombudsman
18 shall—

19 “(1) provide assistance, on a confidential basis, to pro-
20 viders of services and suppliers with respect to complaints,
21 grievances, and requests for information concerning the
22 programs under this title (including provisions of title XI
23 insofar as they relate to this title and are not administered
24 by the Office of the Inspector General of the Department
25 of Health and Human Services) and in the resolution of
26 unclear or conflicting guidance given by the Secretary and
27 medicare contractors to such providers of services and sup-
28 pliers regarding such programs and provisions and require-
29 ments under this title and such provisions; and

30 “(2) submit recommendations to the Secretary for im-
31 provement in the administration of this title and such pro-
32 visions, including—

33 “(A) recommendations to respond to recurring
34 patterns of confusion in this title and such provisions
35 (including recommendations regarding suspending im-
36 position of sanctions where there is widespread confu-
37 sion in program administration), and



1 “(B) recommendations to provide for an appro-
2 priate and consistent response (including not providing
3 for audits) in cases of self-identified overpayments by
4 providers of services and suppliers.

5 The Ombudsman shall not serve as an advocate for any in-
6 creases in payments or new coverage of services, but may iden-
7 tify issues and problems in payment or coverage policies.”.

8 (b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII,
9 as previously amended, is amended by inserting after section
10 1809 the following new section:

11 “MEDICARE BENEFICIARY OMBUDSMAN

12 “SEC. 1810. (a) IN GENERAL.—The Secretary shall ap-
13 point within the Department of Health and Human Services a
14 Medicare Beneficiary Ombudsman who shall have expertise and
15 experience in the fields of health care and education of (and
16 assistance to) individuals entitled to benefits under this title.

17 “(b) DUTIES.—The Medicare Beneficiary Ombudsman
18 shall—

19 “(1) receive complaints, grievances, and requests for
20 information submitted by individuals entitled to benefits
21 under part A or enrolled under part B, or both, with re-
22 spect to any aspect of the medicare program;

23 “(2) provide assistance with respect to complaints,
24 grievances, and requests referred to in paragraph (1),
25 including—

26 “(A) assistance in collecting relevant information
27 for such individuals, to seek an appeal of a decision or
28 determination made by a fiscal intermediary, carrier,
29 Medicare+Choice organization, or the Secretary;

30 “(B) assistance to such individuals with any prob-
31 lems arising from disenrollment from a
32 Medicare+Choice plan under part C; and

33 “(C) assistance to such individuals in presenting
34 information under section 1860D–2(b)(4)(D)(v); and

35 “(3) submit annual reports to Congress and the Sec-
36 retary that describe the activities of the Office and that in-
37 clude such recommendations for improvement in the admin-



1 istration of this title as the Ombudsman determines appro-
2 priate.

3 The Ombudsman shall not serve as an advocate for any in-
4 creases in payments or new coverage of services, but may iden-
5 tify issues and problems in payment or coverage policies.

6 “(c) WORKING WITH HEALTH INSURANCE COUNSELING
7 PROGRAMS.—To the extent possible, the Ombudsman shall
8 work with health insurance counseling programs (receiving
9 funding under section 4360 of Omnibus Budget Reconciliation
10 Act of 1990) to facilitate the provision of information to indi-
11 viduals entitled to benefits under part A or enrolled under part
12 B, or both regarding Medicare+Choice plans and changes to
13 those plans. Nothing in this subsection shall preclude further
14 collaboration between the Ombudsman and such programs.”.

15 (c) DEADLINE FOR APPOINTMENT.—The Secretary shall
16 appoint the Medicare Provider Ombudsman and the Medicare
17 Beneficiary Ombudsman, under the amendments made by sub-
18 sections (a) and (b), respectively, by not later than 1 year after
19 the date of the enactment of this Act.

20 (d) FUNDING.—There are authorized to be appropriated to
21 the Secretary (in appropriate part from the Federal Hospital
22 Insurance Trust Fund and the Federal Supplementary Medical
23 Insurance Trust Fund) to carry out the provisions of sub-
24 section (b) of section 1868 of the Social Security Act (relating
25 to the Medicare Provider Ombudsman), as added by subsection
26 (a)(5) and section 1807 of such Act (relating to the Medicare
27 Beneficiary Ombudsman), as added by subsection (b), such
28 sums as are necessary for fiscal year 2004 and each succeeding
29 fiscal year.

30 (e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
31 MEDICARE).—

32 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE
33 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—
34 Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by
35 adding at the end the following: “The Secretary shall pro-
36 vide, through the toll-free number 1-800-MEDICARE, for
37 a means by which individuals seeking information about, or



1 assistance with, such programs who phone such toll-free
2 number are transferred (without charge) to appropriate en-
3 tities for the provision of such information or assistance.
4 Such toll-free number shall be the toll-free number listed
5 for general information and assistance in the annual notice
6 under subsection (a) instead of the listing of numbers of
7 individual contractors.”.

8 (2) MONITORING ACCURACY.—

9 (A) STUDY.—The Comptroller General of the
10 United States shall conduct a study to monitor the ac-
11 curacy and consistency of information provided to indi-
12 viduals entitled to benefits under part A or enrolled
13 under part B, or both, through the toll-free number 1-
14 800-MEDICARE, including an assessment of whether
15 the information provided is sufficient to answer ques-
16 tions of such individuals. In conducting the study, the
17 Comptroller General shall examine the education and
18 training of the individuals providing information
19 through such number.

20 (B) REPORT.—Not later than 1 year after the
21 date of the enactment of this Act, the Comptroller Gen-
22 eral shall submit to Congress a report on the study
23 conducted under subparagraph (A).

24 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION**
25 **PROGRAM.**

26 (a) IN GENERAL.—The Secretary shall establish a dem-
27 onstration program (in this section referred to as the “dem-
28 onstration program”) under which medicare specialists em-
29 ployed by the Department of Health and Human Services pro-
30 vide advice and assistance to individuals entitled to benefits
31 under part A of title XVIII of the Social Security Act, or en-
32 rolled under part B of such title, or both, regarding the medi-
33 care program at the location of existing local offices of the So-
34 cial Security Administration.

35 (b) LOCATIONS.—

36 (1) IN GENERAL.—The demonstration program shall
37 be conducted in at least 6 offices or areas. Subject to para-



1 graph (2), in selecting such offices and areas, the Secretary
2 shall provide preference for offices with a high volume of
3 visits by individuals referred to in subsection (a).

4 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
5 Secretary shall provide for the selection of at least 2 rural
6 areas to participate in the demonstration program. In con-
7 ducting the demonstration program in such rural areas, the
8 Secretary shall provide for medicare specialists to travel
9 among local offices in a rural area on a scheduled basis.

10 (c) DURATION.—The demonstration program shall be con-
11 ducted over a 3-year period.

12 (d) EVALUATION AND REPORT.—

13 (1) EVALUATION.—The Secretary shall provide for an
14 evaluation of the demonstration program. Such evaluation
15 shall include an analysis of—

16 (A) utilization of, and satisfaction of those individ-
17 uals referred to in subsection (a) with, the assistance
18 provided under the program; and

19 (B) the cost-effectiveness of providing beneficiary
20 assistance through out-stationing medicare specialists
21 at local offices of the Social Security Administration.

22 (2) REPORT.—The Secretary shall submit to Congress
23 a report on such evaluation and shall include in such report
24 recommendations regarding the feasibility of permanently
25 out-stationing medicare specialists at local offices of the So-
26 cial Security Administration.

27 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN**
28 **NOTICES TO BENEFICIARIES ABOUT**
29 **SKILLED NURSING FACILITY BENEFITS.**

30 (a) IN GENERAL.—The Secretary shall provide that in
31 medicare beneficiary notices provided (under section 1806(a) of
32 the Social Security Act, 42 U.S.C. 1395b-7(a)) with respect to
33 the provision of post-hospital extended care services under part
34 A of title XVIII of the Social Security Act, there shall be in-
35 cluded information on the number of days of coverage of such
36 services remaining under such part for the medicare beneficiary
37 and spell of illness involved.



1 (b) EFFECTIVE DATE.—Subsection (a) shall apply to no-
2 tices provided during calendar quarters beginning more than 6
3 months after the date of the enactment of this Act.

4 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**
5 **SKILLED NURSING FACILITIES IN HOSPITAL**
6 **DISCHARGE PLANS.**

7 (a) AVAILABILITY OF DATA.—The Secretary shall publicly
8 provide information that enables hospital discharge planners,
9 medicare beneficiaries, and the public to identify skilled nursing
10 facilities that are participating in the medicare program.

11 (b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL
12 DISCHARGE PLANS.—

13 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C.
14 1395x(ee)(2)(D)) is amended—

15 (A) by striking “hospice services” and inserting
16 “hospice care and post-hospital extended care services”;
17 and

18 (B) by inserting before the period at the end the
19 following: “and, in the case of individuals who are like-
20 ly to need post-hospital extended care services, the
21 availability of such services through facilities that par-
22 ticipate in the program under this title and that serve
23 the area in which the patient resides”.

24 (2) EFFECTIVE DATE.—The amendments made by
25 paragraph (1) shall apply to discharge plans made on or
26 after such date as the Secretary shall specify, but not later
27 than 6 months after the date the Secretary provides for
28 availability of information under subsection (a).

29 **Subtitle D—Appeals and Recovery**

30 **SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDI-**
31 **CARE APPEALS.**

32 (a) TRANSITION PLAN.—

33 (1) IN GENERAL.—Not later than October 1, 2004,
34 the Commissioner of Social Security and the Secretary
35 shall develop and transmit to Congress and the Comptroller
36 General of the United States a plan under which the func-
37 tions of administrative law judges responsible for hearing



1 cases under title XVIII of the Social Security Act (and re-
2 lated provisions in title XI of such Act) are transferred
3 from the responsibility of the Commissioner and the Social
4 Security Administration to the Secretary and the Depart-
5 ment of Health and Human Services.

6 (2) GAO EVALUATION.—The Comptroller General of
7 the United States shall evaluate the plan and, not later
8 than the date that is 6 months after the date on which the
9 plan is received by the Comptroller General, shall submit
10 to Congress a report on such evaluation.

11 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

12 (1) IN GENERAL.—Not earlier than July 1, 2005, and
13 not later than October 1, 2005, the Commissioner of Social
14 Security and the Secretary shall implement the transition
15 plan under subsection (a) and transfer the administrative
16 law judge functions described in such subsection from the
17 Social Security Administration to the Secretary.

18 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-
19 retary shall assure the independence of administrative law
20 judges performing the administrative law judge functions
21 transferred under paragraph (1) from the Centers for
22 Medicare & Medicaid Services and its contractors. In order
23 to assure such independence, the Secretary shall place such
24 judges in an administrative office that is organizationally
25 and functionally separate from such Centers. Such judges
26 shall report to, and be under the general supervision of, the
27 Secretary, but shall not report to, or be subject to super-
28 vision by, another other officer of the Department.

29 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall
30 provide for an appropriate geographic distribution of ad-
31 ministrative law judges performing the administrative law
32 judge functions transferred under paragraph (1) through-
33 out the United States to ensure timely access to such
34 judges.

35 (4) HIRING AUTHORITY.—Subject to the amounts pro-
36 vided in advance in appropriations Act, the Secretary shall
37 have authority to hire administrative law judges to hear



1 such cases, giving priority to those judges with prior experi-
2 ence in handling medicare appeals and in a manner con-
3 sistent with paragraph (3), and to hire support staff for
4 such judges.

5 (5) FINANCING.—Amounts payable under law to the
6 Commissioner for administrative law judges performing the
7 administrative law judge functions transferred under para-
8 graph (1) from the Federal Hospital Insurance Trust Fund
9 and the Federal Supplementary Medical Insurance Trust
10 Fund shall become payable to the Secretary for the func-
11 tions so transferred.

12 (6) SHARED RESOURCES.—The Secretary shall enter
13 into such arrangements with the Commissioner as may be
14 appropriate with respect to transferred functions of admin-
15 istrative law judges to share office space, support staff, and
16 other resources, with appropriate reimbursement from the
17 Trust Funds described in paragraph (5).

18 (c) INCREASED FINANCIAL SUPPORT.—In addition to any
19 amounts otherwise appropriated, to ensure timely action on ap-
20 peals before administrative law judges and the Departmental
21 Appeals Board consistent with section 1869 of the Social Secu-
22 rity Act (as amended by section 521 of BIPA, 114 Stat.
23 2763A–534), there are authorized to be appropriated (in appro-
24 priate part from the Federal Hospital Insurance Trust Fund
25 and the Federal Supplementary Medical Insurance Trust
26 Fund) to the Secretary such sums as are necessary for fiscal
27 year 2005 and each subsequent fiscal year to—

28 (1) increase the number of administrative law judges
29 (and their staffs) under subsection (b)(4);

30 (2) improve education and training opportunities for
31 administrative law judges (and their staffs); and

32 (3) increase the staff of the Departmental Appeals
33 Board.

34 (d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i)
35 (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of
36 BIPA (114 Stat. 2763A–543), is amended by striking “of the
37 Social Security Administration”.



1 **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

2 (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section
3 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is
4 amended—

5 (1) in paragraph (1)(A), by inserting “, subject to
6 paragraph (2),” before “to judicial review of the Sec-
7 retary’s final decision”;

8 (2) in paragraph (1)(F)—

9 (A) by striking clause (ii);

10 (B) by striking “PROCEEDING” and all that follows
11 through “DETERMINATION” and inserting “DETER-
12 MINATIONS AND RECONSIDERATIONS”; and

13 (C) by redesignating subclauses (I) and (II) as
14 clauses (i) and (ii) and by moving the indentation of
15 such subclauses (and the matter that follows) 2 ems to
16 the left; and

17 (3) by adding at the end the following new paragraph:

18 “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall establish
20 a process under which a provider of services or supplier
21 that furnishes an item or service or an individual enti-
22 tled to benefits under part A or enrolled under part B,
23 or both, who has filed an appeal under paragraph (1)
24 may obtain access to judicial review when a review
25 panel (described in subparagraph (D)), on its own mo-
26 tion or at the request of the appellant, determines that
27 no entity in the administrative appeals process has the
28 authority to decide the question of law or regulation
29 relevant to the matters in controversy and that there
30 is no material issue of fact in dispute. The appellant
31 may make such request only once with respect to a
32 question of law or regulation in a case of an appeal.

33 “(B) PROMPT DETERMINATIONS.—If, after or co-
34 incident with appropriately filing a request for an ad-
35 ministrative hearing, the appellant requests a deter-
36 mination by the appropriate review panel that no re-
37 view panel has the authority to decide the question of



1 law or regulations relevant to the matters in con-
2 troversy and that there is no material issue of fact in
3 dispute and if such request is accompanied by the doc-
4 uments and materials as the appropriate review panel
5 shall require for purposes of making such determina-
6 tion, such review panel shall make a determination on
7 the request in writing within 60 days after the date
8 such review panel receives the request and such accom-
9 panying documents and materials. Such a determina-
10 tion by such review panel shall be considered a final de-
11 cision and not subject to review by the Secretary.

12 “(C) ACCESS TO JUDICIAL REVIEW.—

13 “(i) IN GENERAL.—If the appropriate review
14 panel—

15 “(I) determines that there are no material
16 issues of fact in dispute and that the only issue
17 is one of law or regulation that no review panel
18 has the authority to decide; or

19 “(II) fails to make such determination
20 within the period provided under subparagraph
21 (B);

22 then the appellant may bring a civil action as de-
23 scribed in this subparagraph.

24 “(ii) DEADLINE FOR FILING.—Such action
25 shall be filed, in the case described in—

26 “(I) clause (i)(I), within 60 days of date
27 of the determination described in such subpara-
28 graph; or

29 “(II) clause (i)(II), within 60 days of the
30 end of the period provided under subparagraph
31 (B) for the determination.

32 “(iii) VENUE.—Such action shall be brought
33 in the district court of the United States for the ju-
34 dicial district in which the appellant is located (or,
35 in the case of an action brought jointly by more
36 than one applicant, the judicial district in which



1 the greatest number of applicants are located) or in
2 the district court for the District of Columbia.

3 “(iv) INTEREST ON AMOUNTS IN CON-
4 TROVERSY.—Where a provider of services or sup-
5 plier seeks judicial review pursuant to this para-
6 graph, the amount in controversy shall be subject
7 to annual interest beginning on the first day of the
8 first month beginning after the 60-day period as
9 determined pursuant to clause (ii) and equal to the
10 rate of interest on obligations issued for purchase
11 by the Federal Hospital Insurance Trust Fund and
12 by the Federal Supplementary Medical Insurance
13 Trust Fund for the month in which the civil action
14 authorized under this paragraph is commenced, to
15 be awarded by the reviewing court in favor of the
16 prevailing party. No interest awarded pursuant to
17 the preceding sentence shall be deemed income or
18 cost for the purposes of determining reimbursement
19 due providers of services or suppliers under this
20 Act.

21 “(D) REVIEW PANELS.—For purposes of this sub-
22 section, a ‘review panel’ is a panel consisting of 3 mem-
23 bers (who shall be administrative law judges, members
24 of the Departmental Appeals Board, or qualified indi-
25 viduals associated with a qualified independent con-
26 tractor (as defined in subsection (c)(2)) or with another
27 independent entity) designated by the Secretary for
28 purposes of making determinations under this para-
29 graph.”.

30 (b) APPLICATION TO PROVIDER AGREEMENT DETERMINA-
31 TIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is
32 amended—

33 (1) by inserting “(A)” after “(h)(1)”; and

34 (2) by adding at the end the following new subpara-
35 graph:

36 “(B) An institution or agency described in subparagraph
37 (A) that has filed for a hearing under subparagraph (A) shall



1 have expedited access to judicial review under this subpara-
2 graph in the same manner as providers of services, suppliers,
3 and individuals entitled to benefits under part A or enrolled
4 under part B, or both, may obtain expedited access to judicial
5 review under the process established under section 1869(b)(2).
6 Nothing in this subparagraph shall be construed to affect the
7 application of any remedy imposed under section 1819 during
8 the pendency of an appeal under this subparagraph.”

9 (c) EFFECTIVE DATE.—The amendments made by this
10 section shall apply to appeals filed on or after October 1, 2004.

11 (d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREE-
12 MENT DETERMINATIONS.—

13 (1) TERMINATION AND CERTAIN OTHER IMMEDIATE
14 REMEDIES.—The Secretary shall develop and implement a
15 process to expedite proceedings under sections 1866(h) of
16 the Social Security Act (42 U.S.C. 1395cc(h)) in which the
17 remedy of termination of participation, or a remedy de-
18 scribed in clause (i) or (iii) of section 1819(h)(2)(B) of
19 such Act (42 U.S.C. 1395i-3(h)(2)(B)) which is applied on
20 an immediate basis, has been imposed. Under such process
21 priority shall be provided in cases of termination.

22 (2) INCREASED FINANCIAL SUPPORT.—In addition to
23 any amounts otherwise appropriated, to reduce by 50 per-
24 cent the average time for administrative determinations on
25 appeals under section 1866(h) of the Social Security Act
26 (42 U.S.C. 1395cc(h)), there are authorized to be appro-
27 priated (in appropriate part from the Federal Hospital In-
28 surance Trust Fund and the Federal Supplementary Med-
29 ical Insurance Trust Fund) to the Secretary such addi-
30 tional sums for fiscal year 2005 and each subsequent fiscal
31 year as may be necessary. The purposes for which such
32 amounts are available include increasing the number of ad-
33 ministrative law judges (and their staffs) and the appellate
34 level staff at the Departmental Appeals Board of the De-
35 partment of Health and Human Services and educating
36 such judges and staffs on long-term care issues.



1 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

2 (a) **REQUIRING FULL AND EARLY PRESENTATION OF EVI-**
3 **DENCE.—**

4 (1) **IN GENERAL.—**Section 1869(b) (42 U.S.C.
5 1395ff(b)), as amended by BIPA and as amended by sec-
6 tion 932(a), is further amended by adding at the end the
7 following new paragraph:

8 “(3) **REQUIRING FULL AND EARLY PRESENTATION OF**
9 **EVIDENCE BY PROVIDERS.—**A provider of services or sup-
10 plier may not introduce evidence in any appeal under this
11 section that was not presented at the reconsideration con-
12 ducted by the qualified independent contractor under sub-
13 section (c), unless there is good cause which precluded the
14 introduction of such evidence at or before that reconsider-
15 ation.”.

16 (2) **EFFECTIVE DATE.—**The amendment made by
17 paragraph (1) shall take effect on October 1, 2004.

18 (b) **USE OF PATIENTS’ MEDICAL RECORDS.—**Section
19 1869(e)(3)(B)(i) (42 U.S.C. 1395ff(e)(3)(B)(i)), as amended
20 by BIPA, is amended by inserting “(including the medical
21 records of the individual involved)” after “clinical experience”.

22 (c) **NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—**

23 (1) **INITIAL DETERMINATIONS AND REDETERMINA-**
24 **TIONS.—**Section 1869(a) (42 U.S.C. 1395ff(a)), as amend-
25 ed by BIPA, is amended by adding at the end the following
26 new paragraphs:

27 “(4) **REQUIREMENTS OF NOTICE OF DETERMINA-**
28 **TIONS.—**With respect to an initial determination insofar as
29 it results in a denial of a claim for benefits—

30 “(A) the written notice on the determination shall
31 include—

32 “(i) the reasons for the determination, includ-
33 ing whether a local medical review policy or a local
34 coverage determination was used;

35 “(ii) the procedures for obtaining additional
36 information concerning the determination, includ-



1 ing the information described in subparagraph (B);
2 and

3 “(iii) notification of the right to seek a rede-
4 termination or otherwise appeal the determination
5 and instructions on how to initiate such a redeter-
6 mination under this section; and

7 “(B) the person provided such notice may obtain,
8 upon request, the specific provision of the policy, man-
9 ual, or regulation used in making the determination.

10 “(5) REQUIREMENTS OF NOTICE OF REDETERMINA-
11 TIONS.—With respect to a redetermination insofar as it re-
12 sults in a denial of a claim for benefits—

13 “(A) the written notice on the redetermination
14 shall include—

15 “(i) the specific reasons for the redetermina-
16 tion;

17 “(ii) as appropriate, a summary of the clinical
18 or scientific evidence used in making the redeter-
19 mination;

20 “(iii) a description of the procedures for ob-
21 taining additional information concerning the rede-
22 termination; and

23 “(iv) notification of the right to appeal the re-
24 determination and instructions on how to initiate
25 such an appeal under this section;

26 “(B) such written notice shall be provided in
27 printed form and written in a manner calculated to be
28 understood by the individual entitled to benefits under
29 part A or enrolled under part B, or both; and

30 “(C) the person provided such notice may obtain,
31 upon request, information on the specific provision of
32 the policy, manual, or regulation used in making the
33 redetermination.”.

34 (2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42
35 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is
36 amended—



1 (A) by inserting “be written in a manner cal-
2 culated to be understood by the individual entitled to
3 benefits under part A or enrolled under part B, or
4 both, and shall include (to the extent appropriate)”
5 after “in writing, ”; and

6 (B) by inserting “and a notification of the right to
7 appeal such determination and instructions on how to
8 initiate such appeal under this section” after “such de-
9 cision,”.

10 (3) APPEALS.—Section 1869(d) (42 U.S.C.
11 1395ff(d)), as amended by BIPA, is amended—

12 (A) in the heading, by inserting “; NOTICE” after
13 “SECRETARY”; and

14 (B) by adding at the end the following new para-
15 graph:

16 “(4) NOTICE.—Notice of the decision of an adminis-
17 trative law judge shall be in writing in a manner calculated
18 to be understood by the individual entitled to benefits
19 under part A or enrolled under part B, or both, and shall
20 include—

21 “(A) the specific reasons for the determination (in-
22 cluding, to the extent appropriate, a summary of the
23 clinical or scientific evidence used in making the deter-
24 mination);

25 “(B) the procedures for obtaining additional infor-
26 mation concerning the decision; and

27 “(C) notification of the right to appeal the deci-
28 sion and instructions on how to initiate such an appeal
29 under this section.”.

30 (4) SUBMISSION OF RECORD FOR APPEAL.—Section
31 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking
32 “prepare” and inserting “submit” and by striking “with re-
33 spect to” and all that follows through “and relevant poli-
34 cies”.

35 (d) QUALIFIED INDEPENDENT CONTRACTORS.—



1 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDE-
2 PENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C.
3 1395ff(c)(3)), as amended by BIPA, is amended—

4 (A) in subparagraph (A), by striking “sufficient
5 training and expertise in medical science and legal mat-
6 ters” and inserting “sufficient medical, legal, and other
7 expertise (including knowledge of the program under
8 this title) and sufficient staffing”; and

9 (B) by adding at the end the following new sub-
10 paragraph:

11 “(K) INDEPENDENCE REQUIREMENTS.—

12 “(i) IN GENERAL.—Subject to clause (ii), a
13 qualified independent contractor shall not conduct
14 any activities in a case unless the entity—

15 “(I) is not a related party (as defined in
16 subsection (g)(5));

17 “(II) does not have a material familial, fi-
18 nancial, or professional relationship with such a
19 party in relation to such case; and

20 “(III) does not otherwise have a conflict of
21 interest with such a party.

22 “(ii) EXCEPTION FOR REASONABLE COM-
23 PENSATION.—Nothing in clause (i) shall be con-
24 strued to prohibit receipt by a qualified inde-
25 pendent contractor of compensation from the Sec-
26 retary for the conduct of activities under this sec-
27 tion if the compensation is provided consistent with
28 clause (iii).

29 “(iii) LIMITATIONS ON ENTITY COMPENSA-
30 TION.—Compensation provided by the Secretary to
31 a qualified independent contractor in connection
32 with reviews under this section shall not be contin-
33 gent on any decision rendered by the contractor or
34 by any reviewing professional.”.

35 (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—
36 Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is
37 amended—



1 (A) by amending subsection (c)(3)(D) to read as
2 follows:

3 “(D) QUALIFICATIONS FOR REVIEWERS.—The re-
4 quirements of subsection (g) shall be met (relating to
5 qualifications of reviewing professionals).”; and

6 (B) by adding at the end the following new sub-
7 section:

8 “(g) QUALIFICATIONS OF REVIEWERS.—

9 “(1) IN GENERAL.—In reviewing determinations under
10 this section, a qualified independent contractor shall assure
11 that—

12 “(A) each individual conducting a review shall
13 meet the qualifications of paragraph (2);

14 “(B) compensation provided by the contractor to
15 each such reviewer is consistent with paragraph (3);
16 and

17 “(C) in the case of a review by a panel described
18 in subsection (c)(3)(B) composed of physicians or other
19 health care professionals (each in this subsection re-
20 ferred to as a ‘reviewing professional’), a reviewing pro-
21 fessional meets the qualifications described in para-
22 graph (4) and, where a claim is regarding the fur-
23 nishing of treatment by a physician (allopathic or os-
24 teopathic) or the provision of items or services by a
25 physician (allopathic or osteopathic), each reviewing
26 professional shall be a physician (allopathic or osteo-
27 pathic).

28 “(2) INDEPENDENCE.—

29 “(A) IN GENERAL.—Subject to subparagraph (B),
30 each individual conducting a review in a case shall—

31 “(i) not be a related party (as defined in para-
32 graph (5));

33 “(ii) not have a material familial, financial, or
34 professional relationship with such a party in the
35 case under review; and

36 “(iii) not otherwise have a conflict of interest
37 with such a party.



1 “(B) EXCEPTION.—Nothing in subparagraph (A)
2 shall be construed to—

3 “(i) prohibit an individual, solely on the basis
4 of a participation agreement with a fiscal inter-
5 mediary, carrier, or other contractor, from serving
6 as a reviewing professional if—

7 “(I) the individual is not involved in the
8 provision of items or services in the case under
9 review;

10 “(II) the fact of such an agreement is dis-
11 closed to the Secretary and the individual enti-
12 tled to benefits under part A or enrolled under
13 part B, or both, (or authorized representative)
14 and neither party objects; and

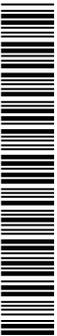
15 “(III) the individual is not an employee of
16 the intermediary, carrier, or contractor and
17 does not provide services exclusively or pri-
18 marily to or on behalf of such intermediary,
19 carrier, or contractor;

20 “(ii) prohibit an individual who has staff privi-
21 leges at the institution where the treatment in-
22 volved takes place from serving as a reviewer mere-
23 ly on the basis of having such staff privileges if the
24 existence of such privileges is disclosed to the Sec-
25 retary and such individual (or authorized represent-
26 ative), and neither party objects; or

27 “(iii) prohibit receipt of compensation by a re-
28 viewing professional from a contractor if the com-
29 pensation is provided consistent with paragraph
30 (3).

31 For purposes of this paragraph, the term ‘participation
32 agreement’ means an agreement relating to the provi-
33 sion of health care services by the individual and does
34 not include the provision of services as a reviewer
35 under this subsection.

36 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—
37 Compensation provided by a qualified independent con-



1 tractor to a reviewer in connection with a review under this
2 section shall not be contingent on the decision rendered by
3 the reviewer.

4 “(4) LICENSURE AND EXPERTISE.—Each reviewing
5 professional shall be—

6 “(A) a physician (allopathic or osteopathic) who is
7 appropriately credentialed or licensed in one or more
8 States to deliver health care services and has medical
9 expertise in the field of practice that is appropriate for
10 the items or services at issue; or

11 “(B) a health care professional who is legally au-
12 thorized in one or more States (in accordance with
13 State law or the State regulatory mechanism provided
14 by State law) to furnish the health care items or serv-
15 ices at issue and has medical expertise in the field of
16 practice that is appropriate for such items or services.

17 “(5) RELATED PARTY DEFINED.—For purposes of this
18 section, the term ‘related party’ means, with respect to a
19 case under this title involving a specific individual entitled
20 to benefits under part A or enrolled under part B, or both,
21 any of the following:

22 “(A) The Secretary, the medicare administrative
23 contractor involved, or any fiduciary, officer, director,
24 or employee of the Department of Health and Human
25 Services, or of such contractor.

26 “(B) The individual (or authorized representative).

27 “(C) The health care professional that provides
28 the items or services involved in the case.

29 “(D) The institution at which the items or services
30 (or treatment) involved in the case are provided.

31 “(E) The manufacturer of any drug or other item
32 that is included in the items or services involved in the
33 case.

34 “(F) Any other party determined under any regu-
35 lations to have a substantial interest in the case in-
36 volved.”.



1 (3) REDUCING MINIMUM NUMBER OF QUALIFIED
2 INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42
3 U.S.C. 1395ff(c)(4)) is amended by striking “not fewer
4 than 12 qualified independent contractors under this sub-
5 section” and inserting “with a sufficient number of quali-
6 fied independent contractors (but not fewer than 4 such
7 contractors) to conduct reconsiderations consistent with the
8 timeframes applicable under this subsection”.

9 (4) EFFECTIVE DATE.—The amendments made by
10 paragraphs (1) and (2) shall be effective as if included in
11 the enactment of the respective provisions of subtitle C of
12 title V of BIPA, (114 Stat. 2763A–534).

13 (5) TRANSITION.—In applying section 1869(g) of the
14 Social Security Act (as added by paragraph (2)), any ref-
15 erence to a medicare administrative contractor shall be
16 deemed to include a reference to a fiscal intermediary
17 under section 1816 of the Social Security Act (42 U.S.C.
18 1395h) and a carrier under section 1842 of such Act (42
19 U.S.C. 1395u).

20 **SEC. 934. PREPAYMENT REVIEW.**

21 (a) IN GENERAL.—Section 1874A, as added by section
22 911(a)(1) and as amended by sections 912(b), 921(b)(1), and
23 921(c)(1), is further amended by adding at the end the fol-
24 lowing new subsection:

25 “(h) CONDUCT OF PREPAYMENT REVIEW.—

26 “(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

27 “(A) IN GENERAL.—A medicare administrative
28 contractor may conduct random prepayment review
29 only to develop a contractor-wide or program-wide
30 claims payment error rates or under such additional
31 circumstances as may be provided under regulations,
32 developed in consultation with providers of services and
33 suppliers.

34 “(B) USE OF STANDARD PROTOCOLS WHEN CON-
35 DUCTING PREPAYMENT REVIEWS.—When a medicare
36 administrative contractor conducts a random prepay-
37 ment review, the contractor may conduct such review



1 only in accordance with a standard protocol for random
2 prepayment audits developed by the Secretary.

3 “(C) CONSTRUCTION.—Nothing in this paragraph
4 shall be construed as preventing the denial of payments
5 for claims actually reviewed under a random prepay-
6 ment review.

7 “(D) RANDOM PREPAYMENT REVIEW.—For pur-
8 poses of this subsection, the term ‘random prepayment
9 review’ means a demand for the production of records
10 or documentation absent cause with respect to a claim.

11 “(2) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-
12 VIEW.—

13 “(A) LIMITATIONS ON INITIATION OF NON-RAN-
14 DOM PREPAYMENT REVIEW.—A medicare administra-
15 tive contractor may not initiate non-random prepay-
16 ment review of a provider of services or supplier based
17 on the initial identification by that provider of services
18 or supplier of an improper billing practice unless there
19 is a likelihood of sustained or high level of payment
20 error (as defined in subsection (i)(3)(A)).

21 “(B) TERMINATION OF NON-RANDOM PREPAY-
22 MENT REVIEW.—The Secretary shall issue regulations
23 relating to the termination, including termination
24 dates, of non-random prepayment review. Such regula-
25 tions may vary such a termination date based upon the
26 differences in the circumstances triggering prepayment
27 review.”.

28 (b) EFFECTIVE DATE.—

29 (1) IN GENERAL.—Except as provided in this sub-
30 section, the amendment made by subsection (a) shall take
31 effect 1 year after the date of the enactment of this Act.

32 (2) DEADLINE FOR PROMULGATION OF CERTAIN REG-
33 ULATIONS.—The Secretary shall first issue regulations
34 under section 1874A(h) of the Social Security Act, as
35 added by subsection (a), by not later than 1 year after the
36 date of the enactment of this Act.



1 (3) APPLICATION OF STANDARD PROTOCOLS FOR RAN-
2 DOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of
3 the Social Security Act, as added by subsection (a), shall
4 apply to random prepayment reviews conducted on or after
5 such date (not later than 1 year after the date of the enact-
6 ment of this Act) as the Secretary shall specify.

7 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-
8 RIERS.—The provisions of section 1874A(h) of the Social Secu-
9 rity Act, as added by subsection (a), shall apply to each fiscal
10 intermediary under section 1816 of the Social Security Act (42
11 U.S.C. 1395h) and each carrier under section 1842 of such Act
12 (42 U.S.C. 1395u) in the same manner as they apply to medi-
13 care administrative contractors under such provisions.

14 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

15 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is
16 amended by adding at the end the following new subsection:

17 “(f) RECOVERY OF OVERPAYMENTS.—

18 “(1) USE OF REPAYMENT PLANS.—

19 “(A) IN GENERAL.—If the repayment, within 30
20 days by a provider of services or supplier, of an over-
21 payment under this title would constitute a hardship
22 (as defined in subparagraph (B)), subject to subpara-
23 graph (C), upon request of the provider of services or
24 supplier the Secretary shall enter into a plan with the
25 provider of services or supplier for the repayment
26 (through offset or otherwise) of such overpayment over
27 a period of at least 6 months but not longer than 3
28 years (or not longer than 5 years in the case of extreme
29 hardship, as determined by the Secretary). Interest
30 shall accrue on the balance through the period of re-
31 payment. Such plan shall meet terms and conditions
32 determined to be appropriate by the Secretary.

33 “(B) HARDSHIP.—

34 “(i) IN GENERAL.—For purposes of subpara-
35 graph (A), the repayment of an overpayment (or
36 overpayments) within 30 days is deemed to con-
37 stitute a hardship if—



1 “(I) in the case of a provider of services
2 that files cost reports, the aggregate amount of
3 the overpayments exceeds 10 percent of the
4 amount paid under this title to the provider of
5 services for the cost reporting period covered by
6 the most recently submitted cost report; or

7 “(II) in the case of another provider of
8 services or supplier, the aggregate amount of
9 the overpayments exceeds 10 percent of the
10 amount paid under this title to the provider of
11 services or supplier for the previous calendar
12 year.

13 “(ii) RULE OF APPLICATION.—The Secretary
14 shall establish rules for the application of this sub-
15 paragraph in the case of a provider of services or
16 supplier that was not paid under this title during
17 the previous year or was paid under this title only
18 during a portion of that year.

19 “(iii) TREATMENT OF PREVIOUS OVERPAY-
20 MENTS.—If a provider of services or supplier has
21 entered into a repayment plan under subparagraph
22 (A) with respect to a specific overpayment amount,
23 such payment amount under the repayment plan
24 shall not be taken into account under clause (i)
25 with respect to subsequent overpayment amounts.

26 “(C) EXCEPTIONS.—Subparagraph (A) shall not
27 apply if—

28 “(i) the Secretary has reason to suspect that
29 the provider of services or supplier may file for
30 bankruptcy or otherwise cease to do business or
31 discontinue participation in the program under this
32 title; or

33 “(ii) there is an indication of fraud or abuse
34 committed against the program.

35 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
36 REPAYMENT PLAN.—If a provider of services or sup-
37 plier fails to make a payment in accordance with a re-



1 payment plan under this paragraph, the Secretary may
2 immediately seek to offset or otherwise recover the
3 total balance outstanding (including applicable interest)
4 under the repayment plan.

5 “(E) RELATION TO NO FAULT PROVISION.—Noth-
6 ing in this paragraph shall be construed as affecting
7 the application of section 1870(c) (relating to no ad-
8 justment in the cases of certain overpayments).

9 “(2) LIMITATION ON RECOUPMENT.—

10 “(A) IN GENERAL.—In the case of a provider of
11 services or supplier that is determined to have received
12 an overpayment under this title and that seeks a recon-
13 sideration by a qualified independent contractor on
14 such determination under section 1869(b)(1), the Sec-
15 retary may not take any action (or authorize any other
16 person, including any medicare contractor, as defined
17 in subparagraph (C)) to recoup the overpayment until
18 the date the decision on the reconsideration has been
19 rendered. If the provisions of section 1869(b)(1) (pro-
20 viding for such a reconsideration by a qualified inde-
21 pendent contractor) are not in effect, in applying the
22 previous sentence any reference to such a reconsider-
23 ation shall be treated as a reference to a redetermina-
24 tion by the fiscal intermediary or carrier involved.

25 “(B) COLLECTION WITH INTEREST.—Insofar as
26 the determination on such appeal is against the pro-
27 vider of services or supplier, interest on the overpay-
28 ment shall accrue on and after the date of the original
29 notice of overpayment. Insofar as such determination
30 against the provider of services or supplier is later re-
31 versed, the Secretary shall provide for repayment of the
32 amount recouped plus interest at the same rate as
33 would apply under the previous sentence for the period
34 in which the amount was recouped.

35 “(C) MEDICARE CONTRACTOR DEFINED.—For
36 purposes of this subsection, the term ‘medicare con-



1 tractor' has the meaning given such term in section
2 1889(g).

3 “(3) LIMITATION ON USE OF EXTRAPOLATION.—A
4 medicare contractor may not use extrapolation to determine
5 overpayment amounts to be recovered by recoupment, off-
6 set, or otherwise unless—

7 “(A) there is a sustained or high level of payment
8 error (as defined by the Secretary by regulation); or

9 “(B) documented educational intervention has
10 failed to correct the payment error (as determined by
11 the Secretary).

12 “(4) PROVISION OF SUPPORTING DOCUMENTATION.—
13 In the case of a provider of services or supplier with respect
14 to which amounts were previously overpaid, a medicare con-
15 tractor may request the periodic production of records or
16 supporting documentation for a limited sample of sub-
17 mitted claims to ensure that the previous practice is not
18 continuing.

19 “(5) CONSENT SETTLEMENT REFORMS.—

20 “(A) IN GENERAL.—The Secretary may use a con-
21 sent settlement (as defined in subparagraph (D)) to
22 settle a projected overpayment.

23 “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-
24 FORMATION BEFORE CONSENT SETTLEMENT OFFER.—
25 Before offering a provider of services or supplier a con-
26 sent settlement, the Secretary shall—

27 “(i) communicate to the provider of services or
28 supplier—

29 “(I) that, based on a review of the medical
30 records requested by the Secretary, a prelimi-
31 nary evaluation of those records indicates that
32 there would be an overpayment;

33 “(II) the nature of the problems identified
34 in such evaluation; and

35 “(III) the steps that the provider of serv-
36 ices or supplier should take to address the
37 problems; and



1 “(ii) provide for a 45-day period during which
2 the provider of services or supplier may furnish ad-
3 ditional information concerning the medical records
4 for the claims that had been reviewed.

5 “(C) CONSENT SETTLEMENT OFFER.—The Sec-
6 retary shall review any additional information furnished
7 by the provider of services or supplier under subpara-
8 graph (B)(ii). Taking into consideration such informa-
9 tion, the Secretary shall determine if there still appears
10 to be an overpayment. If so, the Secretary—

11 “(i) shall provide notice of such determination
12 to the provider of services or supplier, including an
13 explanation of the reason for such determination;
14 and

15 “(ii) in order to resolve the overpayment, may
16 offer the provider of services or supplier—

17 “(I) the opportunity for a statistically
18 valid random sample; or

19 “(II) a consent settlement.

20 The opportunity provided under clause (ii)(I) does not
21 waive any appeal rights with respect to the alleged
22 overpayment involved.

23 “(D) CONSENT SETTLEMENT DEFINED.—For pur-
24 poses of this paragraph, the term ‘consent settlement’
25 means an agreement between the Secretary and a pro-
26 vider of services or supplier whereby both parties agree
27 to settle a projected overpayment based on less than a
28 statistically valid sample of claims and the provider of
29 services or supplier agrees not to appeal the claims in-
30 volved.

31 “(6) NOTICE OF OVER-UTILIZATION OF CODES.—The
32 Secretary shall establish, in consultation with organizations
33 representing the classes of providers of services and sup-
34 pliers, a process under which the Secretary provides for no-
35 tice to classes of providers of services and suppliers served
36 by the contractor in cases in which the contractor has iden-
37 tified that particular billing codes may be overutilized by



1 that class of providers of services or suppliers under the
2 programs under this title (or provisions of title XI insofar
3 as they relate to such programs).

4 “(7) PAYMENT AUDITS.—

5 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
6 DITS.—Subject to subparagraph (C), if a medicare con-
7 tractor decides to conduct a post-payment audit of a
8 provider of services or supplier under this title, the con-
9 tractor shall provide the provider of services or supplier
10 with written notice (which may be in electronic form)
11 of the intent to conduct such an audit.

12 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
13 DITS.—Subject to subparagraph (C), if a medicare con-
14 tractor audits a provider of services or supplier under
15 this title, the contractor shall—

16 “(i) give the provider of services or supplier a
17 full review and explanation of the findings of the
18 audit in a manner that is understandable to the
19 provider of services or supplier and permits the de-
20 velopment of an appropriate corrective action plan;

21 “(ii) inform the provider of services or supplier
22 of the appeal rights under this title as well as con-
23 sent settlement options (which are at the discretion
24 of the Secretary);

25 “(iii) give the provider of services or supplier
26 an opportunity to provide additional information to
27 the contractor; and

28 “(iv) take into account information provided,
29 on a timely basis, by the provider of services or
30 supplier under clause (iii).

31 “(C) EXCEPTION.—Subparagraphs (A) and (B)
32 shall not apply if the provision of notice or findings
33 would compromise pending law enforcement activities,
34 whether civil or criminal, or reveal findings of law en-
35 forcement-related audits.

36 “(8) STANDARD METHODOLOGY FOR PROBE SAM-
37 PLING.—The Secretary shall establish a standard method-



1 ology for medicare contractors to use in selecting a sample
2 of claims for review in the case of an abnormal billing pat-
3 tern.”.

4 (b) EFFECTIVE DATES AND DEADLINES.—

5 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)
6 of the Social Security Act, as added by subsection (a), shall
7 apply to requests for repayment plans made after the date
8 of the enactment of this Act.

9 (2) LIMITATION ON RECOUPMENT.—Section
10 1893(f)(2) of the Social Security Act, as added by sub-
11 section (a), shall apply to actions taken after the date of
12 the enactment of this Act.

13 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of
14 the Social Security Act, as added by subsection (a), shall
15 apply to statistically valid random samples initiated after
16 the date that is 1 year after the date of the enactment of
17 this Act.

18 (4) PROVISION OF SUPPORTING DOCUMENTATION.—
19 Section 1893(f)(4) of the Social Security Act, as added by
20 subsection (a), shall take effect on the date of the enact-
21 ment of this Act.

22 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of
23 the Social Security Act, as added by subsection (a), shall
24 apply to consent settlements entered into after the date of
25 the enactment of this Act.

26 (6) NOTICE OF OVERUTILIZATION.—Not later than 1
27 year after the date of the enactment of this Act, the Sec-
28 retary shall first establish the process for notice of over-
29 utilization of billing codes under section 1893A(f)(6) of the
30 Social Security Act, as added by subsection (a).

31 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the
32 Social Security Act, as added by subsection (a), shall apply
33 to audits initiated after the date of the enactment of this
34 Act.

35 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—
36 Not later than 1 year after the date of the enactment of
37 this Act, the Secretary shall first establish a standard



1 methodology for selection of sample claims for abnormal
2 billing patterns under section 1893(f)(8) of the Social Se-
3 curity Act, as added by subsection (a).

4 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF**
5 **APPEAL.**

6 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
7 amended—

8 (1) by adding at the end of the heading the following:

9 “; ENROLLMENT PROCESSES”; and

10 (2) by adding at the end the following new subsection:

11 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
12 ICES AND SUPPLIERS.—

13 “(1) ENROLLMENT PROCESS.—

14 “(A) IN GENERAL.—The Secretary shall establish
15 by regulation a process for the enrollment of providers
16 of services and suppliers under this title.

17 “(B) DEADLINES.—The Secretary shall establish
18 by regulation procedures under which there are dead-
19 lines for actions on applications for enrollment (and, if
20 applicable, renewal of enrollment). The Secretary shall
21 monitor the performance of medicare administrative
22 contractors in meeting the deadlines established under
23 this subparagraph.

24 “(C) CONSULTATION BEFORE CHANGING PRO-
25 VIDER ENROLLMENT FORMS.—The Secretary shall con-
26 sult with providers of services and suppliers before
27 making changes in the provider enrollment forms re-
28 quired of such providers and suppliers to be eligible to
29 submit claims for which payment may be made under
30 this title.

31 “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-
32 RENEWAL.—A provider of services or supplier whose appli-
33 cation to enroll (or, if applicable, to renew enrollment)
34 under this title is denied may have a hearing and judicial
35 review of such denial under the procedures that apply
36 under subsection (h)(1)(A) to a provider of services that is
37 dissatisfied with a determination by the Secretary.”.



1 (b) EFFECTIVE DATES.—

2 (1) ENROLLMENT PROCESS.—The Secretary shall pro-
3 vide for the establishment of the enrollment process under
4 section 1866(j)(1) of the Social Security Act, as added by
5 subsection (a)(2), within 6 months after the date of the en-
6 actment of this Act.

7 (2) CONSULTATION.—Section 1866(j)(1)(C) of the So-
8 cial Security Act, as added by subsection (a)(2), shall apply
9 with respect to changes in provider enrollment forms made
10 on or after January 1, 2004.

11 (3) HEARING RIGHTS.—Section 1866(j)(2) of the So-
12 cial Security Act, as added by subsection (a)(2), shall apply
13 to denials occurring on or after such date (not later than
14 1 year after the date of the enactment of this Act) as the
15 Secretary specifies.

16 **SEC. 937. PROCESS FOR CORRECTION OF MINOR ER-**
17 **RORS AND OMISSIONS WITHOUT PURSUING**
18 **APPEALS PROCESS.**

19 (a) CLAIMS.—The Secretary shall develop, in consultation
20 with appropriate medicare contractors (as defined in section
21 1889(g) of the Social Security Act, as inserted by section
22 301(a)(1)) and representatives of providers of services and sup-
23 pliers, a process whereby, in the case of minor errors or omis-
24 sions (as defined by the Secretary) that are detected in the sub-
25 mission of claims under the programs under title XVIII of such
26 Act, a provider of services or supplier is given an opportunity
27 to correct such an error or omission without the need to initiate
28 an appeal. Such process shall include the ability to resubmit
29 corrected claims.

30 (b) PERMITTING USE OF CORRECTED AND SUPPLE-
31 MENTARY DATA.—

32 (1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42
33 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after
34 subclause (II) at the end the following:

35 “Notwithstanding subclause (I), a hospital may submit, and the
36 Secretary may accept upon verification, data that corrects or
37 supplements the data described in such subclause without re-



1 gard to whether the corrected or supplementary data relate to
2 a cost report that has been settled.”.

3 (2) EFFECTIVE DATE.—The amendment made by
4 paragraph (1) shall apply to fiscal years beginning with fis-
5 cal year 2004.

6 (3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS
7 PERMITTED FOR FISCAL YEAR 2004.—

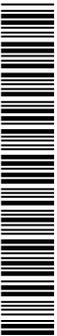
8 (A) IN GENERAL.—Notwithstanding any other
9 provision of law, a hospital may submit (or resubmit)
10 an application for a change described in section
11 1886(d)(10)(C)(i)(II) of the Social Security Act for fis-
12 cal year 2004 if the hospital demonstrates on a timely
13 basis to the satisfaction of the Secretary that the use
14 of corrected or supplementary data under the amend-
15 ment made by paragraph (1) would materially affect
16 the approval of such an application.

17 (B) APPLICATION OF BUDGET NEUTRALITY.—If
18 one or more hospital’s applications are approved as a
19 result of paragraph (1) and subparagraph (A) for fiscal
20 year 2004, the Secretary shall make a proportional ad-
21 justment in the standardized amounts determined
22 under section 1886(d)(3) of the Social Security Act (42
23 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure
24 that approval of such applications does not result in
25 aggregate payments under section 1886(d) of such Act
26 that are greater or less than those that would otherwise
27 be made if paragraph (1) and subparagraph (A) did
28 not apply.

29 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CER-**
30 **TAIN ITEMS AND SERVICES; ADVANCE BENE-**
31 **FICIARY NOTICES.**

32 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as
33 amended by sections 521 and 522 of BIPA and section
34 933(d)(2)(B), is further amended by adding at the end the fol-
35 lowing new subsection:

36 “(h) PRIOR DETERMINATION PROCESS FOR CERTAIN
37 ITEMS AND SERVICES.—



1 “(1) ESTABLISHMENT OF PROCESS.—

2 “(A) IN GENERAL.—With respect to a medicare
3 administrative contractor that has a contract under
4 section 1874A that provides for making payments
5 under this title with respect to eligible items and serv-
6 ices described in subparagraph (C), the Secretary shall
7 establish a prior determination process that meets the
8 requirements of this subsection and that shall be ap-
9 plied by such contractor in the case of eligible request-
10 ers.

11 “(B) ELIGIBLE REQUESTER.—For purposes of
12 this subsection, each of the following shall be an eligi-
13 ble requester:

14 “(i) A physician, but only with respect to eligi-
15 ble items and services for which the physician may
16 be paid directly.

17 “(ii) An individual entitled to benefits under
18 this title, but only with respect to an item or serv-
19 ice for which the individual receives, from the phy-
20 sician who may be paid directly for the item or
21 service, an advance beneficiary notice under section
22 1879(a) that payment may not be made (or may no
23 longer be made) for the item or service under this
24 title.

25 “(C) ELIGIBLE ITEMS AND SERVICES.—For pur-
26 poses of this subsection and subject to paragraph (2),
27 eligible items and services are items and services which
28 are physicians’ services (as defined in paragraph (4)(A)
29 of section 1848(f) for purposes of calculating the sus-
30 tainable growth rate under such section).

31 “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall
32 establish by regulation reasonable limits on the categories
33 of eligible items and services for which a prior determina-
34 tion of coverage may be requested under this subsection. In
35 establishing such limits, the Secretary may consider the
36 dollar amount involved with respect to the item or service,



1 administrative costs and burdens, and other relevant fac-
2 tors.

3 “(3) REQUEST FOR PRIOR DETERMINATION.—

4 “(A) IN GENERAL.—Subject to paragraph (2),
5 under the process established under this subsection an
6 eligible requester may submit to the contractor a re-
7 quest for a determination, before the furnishing of an
8 eligible item or service involved as to whether the item
9 or service is covered under this title consistent with the
10 applicable requirements of section 1862(a)(1)(A) (relat-
11 ing to medical necessity).

12 “(B) ACCOMPANYING DOCUMENTATION.—The Sec-
13 retary may require that the request be accompanied by
14 a description of the item or service, supporting docu-
15 mentation relating to the medical necessity for the item
16 or service, and any other appropriate documentation.
17 In the case of a request submitted by an eligible re-
18 quester who is described in paragraph (1)(B)(ii), the
19 Secretary may require that the request also be accom-
20 panied by a copy of the advance beneficiary notice in-
21 volved.

22 “(4) RESPONSE TO REQUEST.—

23 “(A) IN GENERAL.—Under such process, the con-
24 tractor shall provide the eligible requester with written
25 notice of a determination as to whether—

26 “(i) the item or service is so covered;

27 “(ii) the item or service is not so covered; or

28 “(iii) the contractor lacks sufficient informa-
29 tion to make a coverage determination.

30 If the contractor makes the determination described in
31 clause (iii), the contractor shall include in the notice a
32 description of the additional information required to
33 make the coverage determination.

34 “(B) DEADLINE TO RESPOND.—Such notice shall
35 be provided within the same time period as the time pe-
36 riod applicable to the contractor providing notice of ini-



1 tial determinations on a claim for benefits under sub-
2 section (a)(2)(A).

3 “(C) INFORMING BENEFICIARY IN CASE OF PHYSI-
4 CIAN REQUEST.—In the case of a request in which an
5 eligible requester is not the individual described in
6 paragraph (1)(B)(ii), the process shall provide that the
7 individual to whom the item or service is proposed to
8 be furnished shall be informed of any determination de-
9 scribed in clause (ii) (relating to a determination of
10 non-coverage) and the right (referred to in paragraph
11 (6)(B)) to obtain the item or service and have a claim
12 submitted for the item or service.

13 “(5) EFFECT OF DETERMINATIONS.—

14 “(A) BINDING NATURE OF POSITIVE DETERMINA-
15 TION.—If the contractor makes the determination de-
16 scribed in paragraph (4)(A)(i), such determination
17 shall be binding on the contractor in the absence of
18 fraud or evidence of misrepresentation of facts pre-
19 sented to the contractor.

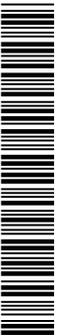
20 “(B) NOTICE AND RIGHT TO REDETERMINATION
21 IN CASE OF A DENIAL.—

22 “(i) IN GENERAL.—If the contractor makes
23 the determination described in paragraph
24 (4)(A)(ii)—

25 “(I) the eligible requester has the right to
26 a redetermination by the contractor on the de-
27 termination that the item or service is not so
28 covered; and

29 “(II) the contractor shall include in notice
30 under paragraph (4)(A) a brief explanation of
31 the basis for the determination, including on
32 what national or local coverage or noncoverage
33 determination (if any) the determination is
34 based, and the right to such a redetermination.

35 “(ii) DEADLINE FOR REDETERMINATIONS.—
36 The contractor shall complete and provide notice of
37 such redetermination within the same time period



1 as the time period applicable to the contractor pro-
2 viding notice of redeterminations relating to a
3 claim for benefits under subsection (a)(3)(C)(ii).

4 “(6) LIMITATION ON FURTHER REVIEW.—

5 “(A) IN GENERAL.—Contractor determinations de-
6 scribed in paragraph (4)(A)(ii) or (4)(A)(iii) (and rede-
7 terminations made under paragraph (5)(B)), relating
8 to pre-service claims are not subject to further adminis-
9 trative appeal or judicial review under this section or
10 otherwise.

11 “(B) DECISION NOT TO SEEK PRIOR DETERMINA-
12 TION OR NEGATIVE DETERMINATION DOES NOT IMPACT
13 RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT,
14 OR APPEAL RIGHTS.—Nothing in this subsection shall
15 be construed as affecting the right of an individual
16 who—

17 “(i) decides not to seek a prior determination
18 under this subsection with respect to items or serv-
19 ices; or

20 “(ii) seeks such a determination and has re-
21 ceived a determination described in paragraph
22 (4)(A)(ii),

23 from receiving (and submitting a claim for) such items
24 services and from obtaining administrative or judicial
25 review respecting such claim under the other applicable
26 provisions of this section. Failure to seek a prior deter-
27 mination under this subsection with respect to items
28 and services shall not be taken into account in such ad-
29 ministrative or judicial review.

30 “(C) NO PRIOR DETERMINATION AFTER RECEIPT
31 OF SERVICES.—Once an individual is provided items
32 and services, there shall be no prior determination
33 under this subsection with respect to such items or
34 services.”.

35 (b) EFFECTIVE DATE; TRANSITION.—

36 (1) EFFECTIVE DATE.—The Secretary shall establish
37 the prior determination process under the amendment



1 made by subsection (a) in such a manner as to provide for
2 the acceptance of requests for determinations under such
3 process filed not later than 18 months after the date of the
4 enactment of this Act.

5 (2) TRANSITION.—During the period in which the
6 amendment made by subsection (a) has become effective
7 but contracts are not provided under section 1874A of the
8 Social Security Act with medicare administrative contrac-
9 tors, any reference in section 1869(g) of such Act (as
10 added by such amendment) to such a contractor is deemed
11 a reference to a fiscal intermediary or carrier with an
12 agreement under section 1816, or contract under section
13 1842, respectively, of such Act.

14 (3) LIMITATION ON APPLICATION TO SGR.—For pur-
15 poses of applying section 1848(f)(2)(D) of the Social Secu-
16 rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment
17 made by subsection (a) shall not be considered to be a
18 change in law or regulation.

19 (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY
20 NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

21 (1) DATA COLLECTION.—The Secretary shall establish
22 a process for the collection of information on the instances
23 in which an advance beneficiary notice (as defined in para-
24 graph (5)) has been provided and on instances in which a
25 beneficiary indicates on such a notice that the beneficiary
26 does not intend to seek to have the item or service that is
27 the subject of the notice furnished.

28 (2) OUTREACH AND EDUCATION.—The Secretary shall
29 establish a program of outreach and education for bene-
30 ficiaries and providers of services and other persons on the
31 appropriate use of advance beneficiary notices and coverage
32 policies under the medicare program.

33 (3) GAO REPORT REPORT ON USE OF ADVANCE BENE-
34 FICIARY NOTICES.—Not later than 18 months after the
35 date on which section 1869(g) of the Social Security Act
36 (as added by subsection (a)) takes effect, the Comptroller
37 General of the United States shall submit to Congress a re-



1 port on the use of advance beneficiary notices under title
2 XVIII of such Act. Such report shall include information
3 concerning the providers of services and other persons that
4 have provided such notices and the response of beneficiaries
5 to such notices.

6 (4) GAO REPORT ON USE OF PRIOR DETERMINATION
7 PROCESS.—Not later than 18 months after the date on
8 which section 1869(g) of the Social Security Act (as added
9 by subsection (a)) takes effect, the Comptroller General of
10 the United States shall submit to Congress a report on the
11 use of the prior determination process under such section.
12 Such report shall include—

13 (A) information concerning the types of proce-
14 dures for which a prior determination has been sought,
15 determinations made under the process, and changes in
16 receipt of services resulting from the application of
17 such process; and

18 (B) an evaluation of whether the process was use-
19 ful for physicians (and other suppliers) and bene-
20 ficiaries, whether it was timely, and whether the
21 amount of information required was burdensome to
22 physicians and beneficiaries.

23 (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In
24 this subsection, the term “advance beneficiary notice”
25 means a written notice provided under section 1879(a)
26 of the Social Security Act (42 U.S.C. 1395pp(a)) to an indi-
27 vidual entitled to benefits under part A or B of title XVIII
28 of such Act before items or services are furnished under
29 such part in cases where a provider of services or other
30 person that would furnish the item or service believes that
31 payment will not be made for some or all of such items or
32 services under such title.



1 **Subtitle V—Miscellaneous Provisions**

2 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUA-**
3 **TION AND MANAGEMENT (E & M) DOCU-**
4 **MENTATION GUIDELINES.**

5 (a) IN GENERAL.—The Secretary may not implement any
6 new documentation guidelines for, or clinical examples of, eval-
7 uation and management physician services under the title
8 XVIII of the Social Security Act on or after the date of the
9 enactment of this Act unless the Secretary—

10 (1) has developed the guidelines in collaboration with
11 practicing physicians (including both generalists and spe-
12 cialists) and provided for an assessment of the proposed
13 guidelines by the physician community;

14 (2) has established a plan that contains specific goals,
15 including a schedule, for improving the use of such guide-
16 lines;

17 (3) has conducted appropriate and representative pilot
18 projects under subsection (b) to test modifications to the
19 evaluation and management documentation guidelines;

20 (4) finds that the objectives described in subsection (c)
21 will be met in the implementation of such guidelines; and

22 (5) has established, and is implementing, a program to
23 educate physicians on the use of such guidelines and that
24 includes appropriate outreach.

25 The Secretary shall make changes to the manner in which ex-
26 isting evaluation and management documentation guidelines
27 are implemented to reduce paperwork burdens on physicians.

28 (b) PILOT PROJECTS TO TEST EVALUATION AND MAN-
29 AGEMENT DOCUMENTATION GUIDELINES.—

30 (1) IN GENERAL.—The Secretary shall conduct under
31 this subsection appropriate and representative pilot projects
32 to test new evaluation and management documentation
33 guidelines referred to in subsection (a).

34 (2) LENGTH AND CONSULTATION.—Each pilot project
35 under this subsection shall—

36 (A) be voluntary;



1 (B) be of sufficient length as determined by the
2 Secretary to allow for preparatory physician and medi-
3 care contractor education, analysis, and use and assess-
4 ment of potential evaluation and management guide-
5 lines; and

6 (C) be conducted, in development and throughout
7 the planning and operational stages of the project, in
8 consultation with practicing physicians (including both
9 generalists and specialists).

10 (3) RANGE OF PILOT PROJECTS.—Of the pilot projects
11 conducted under this subsection—

12 (A) at least one shall focus on a peer review meth-
13 od by physicians (not employed by a medicare con-
14 tractor) which evaluates medical record information for
15 claims submitted by physicians identified as statistical
16 outliers relative to definitions published in the Current
17 Procedures Terminology (CPT) code book of the Amer-
18 ican Medical Association;

19 (B) at least one shall focus on an alternative
20 method to detailed guidelines based on physician docu-
21 mentation of face to face encounter time with a patient;

22 (C) at least one shall be conducted for services
23 furnished in a rural area and at least one for services
24 furnished outside such an area; and

25 (D) at least one shall be conducted in a setting
26 where physicians bill under physicians' services in
27 teaching settings and at least one shall be conducted in
28 a setting other than a teaching setting.

29 (4) BANNING OF TARGETING OF PILOT PROJECT PAR-
30 TICIPANTS.—Data collected under this subsection shall not
31 be used as the basis for overpayment demands or post-pay-
32 ment audits. Such limitation applies only to claims filed as
33 part of the pilot project and lasts only for the duration of
34 the pilot project and only as long as the provider is a par-
35 ticipant in the pilot project.



1 (5) STUDY OF IMPACT.—Each pilot project shall ex-
2 amine the effect of the new evaluation and management
3 documentation guidelines on—

4 (A) different types of physician practices, includ-
5 ing those with fewer than 10 full-time-equivalent em-
6 ployees (including physicians); and

7 (B) the costs of physician compliance, including
8 education, implementation, auditing, and monitoring.

9 (6) PERIODIC REPORTS.—The Secretary shall submit
10 to Congress periodic reports on the pilot projects under this
11 subsection.

12 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
13 GUIDELINES.—The objectives for modified evaluation and man-
14 agement documentation guidelines developed by the Secretary
15 shall be to—

16 (1) identify clinically relevant documentation needed to
17 code accurately and assess coding levels accurately;

18 (2) decrease the level of non-clinically pertinent and
19 burdensome documentation time and content in the physi-
20 cian's medical record;

21 (3) increase accuracy by reviewers; and

22 (4) educate both physicians and reviewers.

23 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
24 UMENTATION FOR PHYSICIAN CLAIMS.—

25 (1) STUDY.—The Secretary shall carry out a study of
26 the matters described in paragraph (2).

27 (2) MATTERS DESCRIBED.—The matters referred to in
28 paragraph (1) are—

29 (A) the development of a simpler, alternative sys-
30 tem of requirements for documentation accompanying
31 claims for evaluation and management physician serv-
32 ices for which payment is made under title XVIII of
33 the Social Security Act; and

34 (B) consideration of systems other than current
35 coding and documentation requirements for payment
36 for such physician services.



1 (3) CONSULTATION WITH PRACTICING PHYSICIANS.—
2 In designing and carrying out the study under paragraph
3 (1), the Secretary shall consult with practicing physicians,
4 including physicians who are part of group practices and
5 including both generalists and specialists.

6 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
7 QUIREMENTS.—In developing an alternative system under
8 paragraph (2), the Secretary shall consider requirements of
9 administrative simplification under part C of title XI of the
10 Social Security Act.

11 (5) REPORT TO CONGRESS.—(A) Not later than Octo-
12 ber 1, 2005, the Secretary shall submit to Congress a re-
13 port on the results of the study conducted under paragraph
14 (1).

15 (B) The Medicare Payment Advisory Commission shall
16 conduct an analysis of the results of the study included in
17 the report under subparagraph (A) and shall submit a re-
18 port on such analysis to Congress.

19 (e) STUDY ON APPROPRIATE CODING OF CERTAIN EX-
20 TENDED OFFICE VISITS.—The Secretary shall conduct a study
21 of the appropriateness of coding in cases of extended office vis-
22 its in which there is no diagnosis made. Not later than October
23 1, 2005, the Secretary shall submit a report to Congress on
24 such study and shall include recommendations on how to code
25 appropriately for such visits in a manner that takes into ac-
26 count the amount of time the physician spent with the patient.

27 (f) DEFINITIONS.—In this section—

28 (1) the term “rural area” has the meaning given that
29 term in section 1886(d)(2)(D) of the Social Security Act,
30 42 U.S.C. 1395ww(d)(2)(D); and

31 (2) the term “teaching settings” are those settings de-
32 scribed in section 415.150 of title 42, Code of Federal Reg-
33 ulations.



1 **SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECH-**
2 **NOLOGY AND COVERAGE.**

3 (a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Sec-
4 tion 1868 (42 U.S.C. 1395ee), as amended by section 921(a),
5 is amended by adding at the end the following new subsection:

6 “(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

7 “(1) ESTABLISHMENT.—The Secretary shall establish
8 a Council for Technology and Innovation within the Cen-
9 ters for Medicare & Medicaid Services (in this section re-
10 ferred to as ‘CMS’).

11 “(2) COMPOSITION.—The Council shall be composed
12 of senior CMS staff and clinicians and shall be chaired by
13 the Executive Coordinator for Technology and Innovation
14 (appointed or designated under paragraph (4)).

15 “(3) DUTIES.—The Council shall coordinate the activi-
16 ties of coverage, coding, and payment processes under this
17 title with respect to new technologies and procedures, in-
18 cluding new drug therapies, and shall coordinate the ex-
19 change of information on new technologies between CMS
20 and other entities that make similar decisions.

21 “(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY
22 AND INNOVATION.—The Secretary shall appoint (or des-
23 ignate) a noncareer appointee (as defined in section
24 3132(a)(7) of title 5, United States Code) who shall serve
25 as the Executive Coordinator for Technology and Innova-
26 tion. Such executive coordinator shall report to the Admin-
27 istrator of CMS, shall chair the Council, shall oversee the
28 execution of its duties, and shall serve as a single point of
29 contact for outside groups and entities regarding the cov-
30 erage, coding, and payment processes under this title.”.

31 (b) METHODS FOR DETERMINING PAYMENT BASIS FOR
32 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 13951(h)) is
33 amended by adding at the end the following:

34 “(8)(A) The Secretary shall establish by regulation proce-
35 dures for determining the basis for, and amount of, payment
36 under this subsection for any clinical diagnostic laboratory test
37 with respect to which a new or substantially revised HCPCS



1 code is assigned on or after January 1, 2005 (in this para-
2 graph referred to as ‘new tests’).

3 “(B) Determinations under subparagraph (A) shall be
4 made only after the Secretary—

5 “(i) makes available to the public (through an Internet
6 site and other appropriate mechanisms) a list that includes
7 any such test for which establishment of a payment amount
8 under this subsection is being considered for a year;

9 “(ii) on the same day such list is made available,
10 causes to have published in the Federal Register notice of
11 a meeting to receive comments and recommendations (and
12 data on which recommendations are based) from the public
13 on the appropriate basis under this subsection for estab-
14 lishing payment amounts for the tests on such list;

15 “(iii) not less than 30 days after publication of such
16 notice convenes a meeting, that includes representatives of
17 officials of the Centers for Medicare & Medicaid Services
18 involved in determining payment amounts, to receive such
19 comments and recommendations (and data on which the
20 recommendations are based);

21 “(iv) taking into account the comments and rec-
22 ommendations (and accompanying data) received at such
23 meeting, develops and makes available to the public
24 (through an Internet site and other appropriate mecha-
25 nisms) a list of proposed determinations with respect to the
26 appropriate basis for establishing a payment amount under
27 this subsection for each such code, together with an expla-
28 nation of the reasons for each such determination, the data
29 on which the determinations are based, and a request for
30 public written comments on the proposed determination;
31 and

32 “(v) taking into account the comments received during
33 the public comment period, develops and makes available to
34 the public (through an Internet site and other appropriate
35 mechanisms) a list of final determinations of the payment
36 amounts for such tests under this subsection, together with
37 the rationale for each such determination, the data on



1 which the determinations are based, and responses to com-
2 ments and suggestions received from the public.

3 “(C) Under the procedures established pursuant to sub-
4 paragraph (A), the Secretary shall—

5 “(i) set forth the criteria for making determinations
6 under subparagraph (A); and

7 “(ii) make available to the public the data (other than
8 proprietary data) considered in making such determina-
9 tions.

10 “(D) The Secretary may convene such further public meet-
11 ings to receive public comments on payment amounts for new
12 tests under this subsection as the Secretary deems appropriate.

13 “(E) For purposes of this paragraph:

14 “(i) The term ‘HCPCS’ refers to the Health Care Pro-
15 cedure Coding System.

16 “(ii) A code shall be considered to be ‘substantially re-
17 vised’ if there is a substantive change to the definition of
18 the test or procedure to which the code applies (such as a
19 new analyte or a new methodology for measuring an exist-
20 ing analyte-specific test).”.

21 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
22 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
23 MENT SYSTEM.—

24 (1) STUDY.—The Comptroller General of the United
25 States shall conduct a study that analyzes which external
26 data can be collected in a shorter time frame by the Cen-
27 ters for Medicare & Medicaid Services for use in computing
28 payments for inpatient hospital services. The study may in-
29 clude an evaluation of the feasibility and appropriateness of
30 using of quarterly samples or special surveys or any other
31 methods. The study shall include an analysis of whether
32 other executive agencies, such as the Bureau of Labor Sta-
33 tistics in the Department of Commerce, are best suited to
34 collect this information.

35 (2) REPORT.—By not later than October 1, 2004, the
36 Comptroller General shall submit a report to Congress on
37 the study under paragraph (1).



1 (d) PROCESS FOR ADOPTION OF ICD CODES AS DATA
2 STANDARD.—Section 1172(f) (42 U.S.C. 1320d-1(f)) is
3 amended by inserting after the first sentence the following:
4 “Notwithstanding the preceding sentence, if the National Com-
5 mittee on Vital and Health Statistics has not made a rec-
6 ommendation to the Secretary before the date of the enactment
7 of this sentence, with respect to the adoption of the Inter-
8 national Classification of Diseases, 10th Revision, Procedure
9 Coding System (‘ICD-10-PCS’) and the International Classi-
10 fication of Diseases, 10th Revision, Clinical Modification
11 (‘ICD-10-CM’) as a standard under this part for the reporting
12 of diagnoses, the Secretary may implement ICD-10-PCS only
13 with respect to inpatient services as such a standard.”.

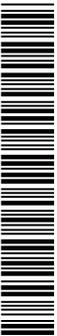
14 **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN**
15 **SERVICES UNDER MEDICARE SECONDARY**
16 **PAYOR (MSP) PROVISIONS.**

17 (a) IN GENERAL.—The Secretary shall not require a hos-
18 pital (including a critical access hospital) to ask questions (or
19 obtain information) relating to the application of section
20 1862(b) of the Social Security Act (relating to medicare sec-
21 ondary payor provisions) in the case of reference laboratory
22 services described in subsection (b), if the Secretary does not
23 impose such requirement in the case of such services furnished
24 by an independent laboratory.

25 (b) REFERENCE LABORATORY SERVICES DESCRIBED.—
26 Reference laboratory services described in this subsection are
27 clinical laboratory diagnostic tests (or the interpretation of
28 such tests, or both) furnished without a face-to-face encounter
29 between the individual entitled to benefits under part A or en-
30 rolled under part B, or both, and the hospital involved and in
31 which the hospital submits a claim only for such test or inter-
32 pretation.

33 **SEC. 944. EMTALA IMPROVEMENTS.**

34 (a) PAYMENT FOR EMTALA-MANDATED SCREENING AND
35 STABILIZATION SERVICES.—



1 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
2 amended by inserting after subsection (c) the following new
3 subsection:

4 “(d) For purposes of subsection (a)(1)(A), in the case of
5 any item or service that is required to be provided pursuant to
6 section 1867 to an individual who is entitled to benefits under
7 this title, determinations as to whether the item or service is
8 reasonable and necessary shall be made on the basis of the in-
9 formation available to the treating physician or practitioner (in-
10 cluding the patient’s presenting symptoms or complaint) at the
11 time the item or service was ordered or furnished by the physi-
12 cian or practitioner (and not on the patient’s principal diag-
13 nosis). When making such determinations with respect to such
14 an item or service, the Secretary shall not consider the fre-
15 quency with which the item or service was provided to the pa-
16 tient before or after the time of the admission or visit.”.

17 (2) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply to items and services furnished
19 on or after January 1, 2004.

20 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA IN-
21 VESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C.
22 1395dd(d)) is amended by adding at the end the following new
23 paragraph:

24 “(4) NOTICE UPON CLOSING AN INVESTIGATION.—The
25 Secretary shall establish a procedure to notify hospitals and
26 physicians when an investigation under this section is
27 closed.”.

28 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN
29 EMTALA CASES INVOLVING TERMINATION OF PARTICIPA-
30 TION.—

31 (1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C.
32 1395dd(d)(3)) is amended—

33 (A) in the first sentence, by inserting “or in termi-
34 nating a hospital’s participation under this title” after
35 “in imposing sanctions under paragraph (1)”; and

36 (B) by adding at the end the following new sen-
37 tences: “Except in the case in which a delay would



1 pediatric subspecialty, obstetrics-gynecology, and psychi-
2 atry, with not more than one physician from any particular
3 field;

4 (3) 2 shall represent patients;

5 (4) 2 shall be staff involved in EMTALA investiga-
6 tions from different regional offices of the Centers for
7 Medicare & Medicaid Services; and

8 (5) 1 shall be from a State survey office involved in
9 EMTALA investigations and 1 shall be from a peer review
10 organization, both of whom shall be from areas other than
11 the regions represented under paragraph (4).

12 In selecting members described in paragraphs (1) through (3),
13 the Secretary shall consider qualified individuals nominated by
14 organizations representing providers and patients.

15 (c) GENERAL RESPONSIBILITIES.—The Advisory Group—

16 (1) shall review EMTALA regulations;

17 (2) may provide advice and recommendations to the
18 Secretary with respect to those regulations and their appli-
19 cation to hospitals and physicians;

20 (3) shall solicit comments and recommendations from
21 hospitals, physicians, and the public regarding the imple-
22 mentation of such regulations; and

23 (4) may disseminate information on the application of
24 such regulations to hospitals, physicians, and the public.

25 (d) ADMINISTRATIVE MATTERS.—

26 (1) CHAIRPERSON.—The members of the Advisory
27 Group shall elect a member to serve as chairperson of the
28 Advisory Group for the life of the Advisory Group.

29 (2) MEETINGS.—The Advisory Group shall first meet
30 at the direction of the Secretary. The Advisory Group shall
31 then meet twice per year and at such other times as the
32 Advisory Group may provide.

33 (e) TERMINATION.—The Advisory Group shall terminate
34 30 months after the date of its first meeting.

35 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Sec-
36 retary shall establish the Advisory Group notwithstanding any
37 limitation that may apply to the number of advisory committees



1 that may be established (within the Department of Health and
2 Human Services or otherwise).

3 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO**
4 **PROVIDE CORE HOSPICE SERVICES IN CER-**
5 **TAIN CIRCUMSTANCES.**

6 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
7 1395x(dd)(5)) is amended by adding at the end the following:

8 “(D) In extraordinary, exigent, or other non-routine cir-
9 cumstances, such as unanticipated periods of high patient
10 loads, staffing shortages due to illness or other events, or tem-
11 porary travel of a patient outside a hospice program’s service
12 area, a hospice program may enter into arrangements with an-
13 other hospice program for the provision by that other program
14 of services described in paragraph (2)(A)(ii)(I). The provisions
15 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-
16 ices provided under such arrangements.

17 “(E) A hospice program may provide services described in
18 paragraph (1)(A) other than directly by the program if the
19 services are highly specialized services of a registered profes-
20 sional nurse and are provided non-routinely and so infrequently
21 so that the provision of such services directly would be imprac-
22 ticable and prohibitively expensive.”.

23 (b) CONFORMING PAYMENT PROVISION.—Section 1814(i)
24 (42 U.S.C. 1395f(i)) is amended by adding at the end the fol-
25 lowing new paragraph:

26 “(4) In the case of hospice care provided by a hospice pro-
27 gram under arrangements under section 1861(dd)(5)(D) made
28 by another hospice program, the hospice program that made
29 the arrangements shall bill and be paid for the hospice care.”.

30 (c) EFFECTIVE DATE.—The amendments made by this
31 section shall apply to hospice care provided on or after the date
32 of the enactment of this Act.

33 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**
34 **GENS STANDARD TO CERTAIN HOSPITALS.**

35 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
36 amended—

37 (1) in subsection (a)(1)—



1 (A) in subparagraph (R), by striking “and” at the
2 end;

3 (B) in subparagraph (S), by striking the period at
4 the end and inserting “, and”; and

5 (C) by inserting after subparagraph (S) the fol-
6 lowing new subparagraph:

7 “(T) in the case of hospitals that are not otherwise
8 subject to the Occupational Safety and Health Act of 1970,
9 to comply with the Bloodborne Pathogens standard under
10 section 1910.1030 of title 29 of the Code of Federal Regu-
11 lations (or as subsequently redesignated).”; and

12 (2) by adding at the end of subsection (b) the fol-
13 lowing new paragraph:

14 “(4)(A) A hospital that fails to comply with the require-
15 ment of subsection (a)(1)(T) (relating to the Bloodborne
16 Pathogens standard) is subject to a civil money penalty in an
17 amount described in subparagraph (B), but is not subject to
18 termination of an agreement under this section.

19 “(B) The amount referred to in subparagraph (A) is an
20 amount that is similar to the amount of civil penalties that may
21 be imposed under section 17 of the Occupational Safety and
22 Health Act of 1970 for a violation of the Bloodborne Pathogens
23 standard referred to in subsection (a)(1)(T) by a hospital that
24 is subject to the provisions of such Act.

25 “(C) A civil money penalty under this paragraph shall be
26 imposed and collected in the same manner as civil money pen-
27 alties under subsection (a) of section 1128A are imposed and
28 collected under that section.”.

29 (b) EFFECTIVE DATE.—The amendments made by this
30 subsection (a) shall apply to hospitals as of July 1, 2004.

31 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**
32 **CORRECTIONS.**

33 (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY
34 COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of
35 section 1114 (42 U.S.C. 1314)—

36 (A) is transferred to section 1862 and added at the
37 end of such section; and



1 (B) is redesignated as subsection (j).
2 (2) Section 1862 (42 U.S.C. 1395y) is amended—
3 (A) in the last sentence of subsection (a), by striking
4 “established under section 1114(f)”; and
5 (B) in subsection (j), as so transferred and
6 redesignated—
7 (i) by striking “under subsection (f)”; and
8 (ii) by striking “section 1862(a)(1)” and inserting
9 “subsection (a)(1)”.
10 (b) TERMINOLOGY CORRECTIONS.—(1) Section
11 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by
12 section 521 of BIPA, is amended—
13 (A) in subclause (III), by striking “policy” and insert-
14 ing “determination”; and
15 (B) in subclause (IV), by striking “medical review
16 policies” and inserting “coverage determinations”.
17 (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C))
18 is amended by striking “policy” and “POLICY” and inserting
19 “determination” each place it appears and “DETERMINATION”,
20 respectively.
21 (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42
22 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is
23 amended—
24 (1) in subparagraph (A)(iv), by striking “subclause
25 (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;
26 (2) in subparagraph (B), by striking “clause (i)(IV)”
27 and “clause (i)(III)” and inserting “subparagraph (A)(iv)”
28 and “subparagraph (A)(iii)”, respectively; and
29 (3) in subparagraph (C), by striking “clause (i)”,
30 “subclause (IV)” and “subparagraph (A)” and inserting
31 “subparagraph (A)”, “clause (iv)” and “paragraph
32 (1)(A)”, respectively each place it appears.
33 (d) OTHER CORRECTIONS.—Effective as if included in the
34 enactment of section 521(c) of BIPA, section 1154(e) (42
35 U.S.C. 1320c-3(e)) is amended by striking paragraph (5).



1 (e) EFFECTIVE DATE.—Except as otherwise provided, the
2 amendments made by this section shall be effective as if in-
3 cluded in the enactment of BIPA.

4 **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PRO-**
5 **GRAM EXCLUSION.**

6 The first sentence of section 1128(c)(3)(B) (42 U.S.C.
7 1320a-7(c)(3)(B)) is amended to read as follows: “Subject to
8 subparagraph (G), in the case of an exclusion under subsection
9 (a), the minimum period of exclusion shall be not less than five
10 years, except that, upon the request of the administrator of a
11 Federal health care program (as defined in section 1128B(f))
12 who determines that the exclusion would impose a hardship on
13 individuals entitled to benefits under part A of title XVIII or
14 enrolled under part B of such title, or both, the Secretary may
15 waive the exclusion under subsection (a)(1), (a)(3), or (a)(4)
16 with respect to that program in the case of an individual or en-
17 tity that is the sole community physician or sole source of es-
18 sential specialized services in a community.”.

19 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

20 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
21 amended by adding after subsection (g) the following new sub-
22 section:

23 “(h)(1) Subject to paragraph (2), a group health plan (as
24 defined in subsection (a)(1)(A)(v)) providing supplemental or
25 secondary coverage to individuals also entitled to services under
26 this title shall not require a medicare claims determination
27 under this title for dental benefits specifically excluded under
28 subsection (a)(12) as a condition of making a claims deter-
29 mination for such benefits under the group health plan.

30 “(2) A group health plan may require a claims determina-
31 tion under this title in cases involving or appearing to involve
32 inpatient dental hospital services or dental services expressly
33 covered under this title pursuant to actions taken by the Sec-
34 retary.”.

35 (b) EFFECTIVE DATE.—The amendment made by sub-
36 section (a) shall take effect on the date that is 60 days after
37 the date of the enactment of this Act.



1 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION**
2 **TO COMPUTE DSH FORMULA.**

3 Beginning not later than 1 year after the date of the en-
4 actment of this Act, the Secretary shall furnish to subsection
5 (d) hospitals (as defined in section 1886(d)(1)(B) of the Social
6 Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary
7 for such hospitals to compute the number of patient days de-
8 scribed in subclause (II) of section 1886(d)(5)(F)(vi) of the So-
9 cial Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in
10 computing the disproportionate patient percentage under such
11 section for that hospital. Such data shall also be furnished to
12 other hospitals which would qualify for additional payments
13 under part A of title XVIII of the Social Security Act on the
14 basis of such data.

15 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

16 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.
17 1395u(b)(6)(A)) is amended by striking “or (ii) (where the
18 service was provided in a hospital, critical access hospital, clin-
19 ic, or other facility) to the facility in which the service was pro-
20 vided if there is a contractual arrangement between such physi-
21 cian or other person and such facility under which such facility
22 submits the bill for such service,” and inserting “or (ii) where
23 the service was provided under a contractual arrangement be-
24 tween such physician or other person and an entity (as defined
25 by the Secretary), to the entity if, under the contractual ar-
26 rangement, the entity submits the bill for the service and the
27 contractual arrangement meets such other program integrity
28 and other safeguards as the Secretary may determine to be ap-
29 propriate,”.

30 (b) CONFORMING AMENDMENT.—The second sentence of
31 section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by
32 striking “except to an employer or facility” and inserting “ex-
33 cept to an employer, entity, or other person”.

34 (c) EFFECTIVE DATE.—The amendments made by section
35 shall apply to payments made on or after the date of the enact-
36 ment of this Act.



1 **SEC. 953. OTHER PROVISIONS.**

2 (a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

3 (1) SUSTAINABLE GROWTH RATE AND UPDATES.—

4 Not later than 6 months after the date of the enactment
5 of this Act, the Comptroller General of the United States
6 shall submit to Congress a report on the appropriateness
7 of the updates in the conversion factor under subsection
8 (d)(3) of section 1848 of the Social Security Act (42
9 U.S.C. 1395w-4), including the appropriateness of the sus-
10 tainable growth rate formula under subsection (f) of such
11 section for 2002 and succeeding years. Such report shall
12 examine the stability and predictability of such updates and
13 rate and alternatives for the use of such rate in the up-
14 dates.

15 (2) PHYSICIAN COMPENSATION GENERALLY.—Not

16 later than 12 months after the date of the enactment of
17 this Act, the Comptroller General shall submit to Congress
18 a report on all aspects of physician compensation for serv-
19 ices furnished under title XVIII of the Social Security Act,
20 and how those aspects interact and the effect on appro-
21 priate compensation for physician services. Such report
22 shall review alternatives for the physician fee schedule
23 under section 1848 of such title (42 U.S.C. 1395w-4).

24 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL COV-

25 ERAGE DETERMINATIONS.—The Secretary shall provide, in an
26 appropriate annual publication available to the public, a list of
27 national coverage determinations made under title XVIII of the
28 Social Security Act in the previous year and information on
29 how to get more information with respect to such determina-
30 tions.

31 (c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME

32 HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO
33 ARE NOT MEDICARE BENEFICIARIES.—Not later than 6
34 months after the date of the enactment of this Act, the Comp-
35 troller General of the United States shall submit to Congress
36 a report on the implications if there were flexibility in the ap-
37 plication of the medicare conditions of participation for home



1 health agencies with respect to groups or types of patients who
2 are not medicare beneficiaries. The report shall include an
3 analysis of the potential impact of such flexible application on
4 clinical operations and the recipients of such services and an
5 analysis of methods for monitoring the quality of care provided
6 to such recipients.

7 (d) **OIG REPORT ON NOTICES RELATING TO USE OF**
8 **HOSPITAL LIFETIME RESERVE DAYS.**—Not later than 1 year
9 after the date of the enactment of this Act, the Inspector Gen-
10 eral of the Department of Health and Human Services shall
11 submit a report to Congress on—

12 (1) the extent to which hospitals provide notice to
13 medicare beneficiaries in accordance with applicable re-
14 quirements before they use the 60 lifetime reserve days de-
15 scribed in section 1812(a)(1) of the Social Security Act (42
16 U.S.C. 1395d(a)(1)); and

17 (2) the appropriateness and feasibility of hospitals pro-
18 viding a notice to such beneficiaries before they completely
19 exhaust such lifetime reserve days.

20 **TITLE X—IMPORTATION OF**
21 **PRESCRIPTION DRUGS**

22 **SEC. 1001. IMPORTATION OF PRESCRIPTION DRUGS.**

23 (a) **IN GENERAL.**—Chapter VIII of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended
25 by striking section 804 and inserting the following:

26 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

27 “(a) **DEFINITIONS.**—In this section:

28 “(1) **IMPORTER.**—The term ‘importer’ means a phar-
29 macist or wholesaler.

30 “(2) **PHARMACIST.**—The term ‘pharmacist’ means a
31 person licensed by a State to practice pharmacy, including
32 the dispensing and selling of prescription drugs.

33 “(3) **PRESCRIPTION DRUG.**—The term ‘prescription
34 drug’ means a drug subject to section 503(b), other than—

35 “(A) a controlled substance (as defined in section
36 102 of the Controlled Substances Act (21 U.S.C. 802));



1 “(B) a biological product (as defined in section
2 351 of the Public Health Service Act (42 U.S.C. 262));

3 “(C) an infused drug (including a peritoneal dialy-
4 sis solution);

5 “(D) an intravenously injected drug; or

6 “(E) a drug that is inhaled during surgery.

7 “(4) QUALIFYING LABORATORY.—The term ‘qualifying
8 laboratory’ means a laboratory in the United States that
9 has been approved by the Secretary for the purposes of this
10 section.

11 “(5) WHOLESALER.—

12 “(A) IN GENERAL.—The term ‘wholesaler’ means
13 a person licensed as a wholesaler or distributor of pre-
14 scription drugs in the United States under section
15 503(e)(2)(A).

16 “(B) EXCLUSION.—The term ‘wholesaler’ does not
17 include a person authorized to import drugs under sec-
18 tion 801(d)(1).

19 “(b) REGULATIONS.—The Secretary, after consultation
20 with the United States Trade Representative and the Commis-
21 sioner of Customs, shall promulgate regulations permitting
22 pharmacists and wholesalers to import prescription drugs from
23 Canada into the United States.

24 “(c) LIMITATION.—The regulations under subsection (b)
25 shall—

26 “(1) require that safeguards be in place to ensure that
27 each prescription drug imported under the regulations com-
28 plies with section 505 (including with respect to being safe
29 and effective for the intended use of the prescription drug),
30 with sections 501 and 502, and with other applicable re-
31 quirements of this Act;

32 “(2) require that an importer of a prescription drug
33 under the regulations comply with subsections (d)(1) and
34 (e); and

35 “(3) contain any additional provisions determined by
36 the Secretary to be appropriate as a safeguard to protect



1 the public health or as a means to facilitate the importation
2 of prescription drugs.

3 “(d) INFORMATION AND RECORDS.—

4 “(1) IN GENERAL.—The regulations under subsection
5 (b) shall require an importer of a prescription drug under
6 subsection (b) to submit to the Secretary the following in-
7 formation and documentation:

8 “(A) The name and quantity of the active ingre-
9 dient of the prescription drug.

10 “(B) A description of the dosage form of the pre-
11 scription drug.

12 “(C) The date on which the prescription drug is
13 shipped.

14 “(D) The quantity of the prescription drug that is
15 shipped.

16 “(E) The point of origin and destination of the
17 prescription drug.

18 “(F) The price paid by the importer for the pre-
19 scription drug.

20 “(G) Documentation from the foreign seller
21 specifying—

22 “(i) the original source of the prescription
23 drug; and

24 “(ii) the quantity of each lot of the prescrip-
25 tion drug originally received by the seller from that
26 source.

27 “(H) The lot or control number assigned to the
28 prescription drug by the manufacturer of the prescrip-
29 tion drug.

30 “(I) The name, address, telephone number, and
31 professional license number (if any) of the importer.

32 “(J)(i) In the case of a prescription drug that is
33 shipped directly from the first foreign recipient of the
34 prescription drug from the manufacturer:

35 “(I) Documentation demonstrating that the
36 prescription drug was received by the recipient



1 from the manufacturer and subsequently shipped
2 by the first foreign recipient to the importer.

3 “(II) Documentation of the quantity of each
4 lot of the prescription drug received by the first
5 foreign recipient demonstrating that the quantity
6 being imported into the United States is not more
7 than the quantity that was received by the first for-
8 eign recipient.

9 “(III)(aa) In the case of an initial imported
10 shipment, documentation demonstrating that each
11 batch of the prescription drug in the shipment was
12 statistically sampled and tested for authenticity
13 and degradation.

14 “(bb) In the case of any subsequent shipment,
15 documentation demonstrating that a statistically
16 valid sample of the shipment was tested for authen-
17 ticity and degradation.

18 “(ii) In the case of a prescription drug that is not
19 shipped directly from the first foreign recipient of the
20 prescription drug from the manufacturer, documenta-
21 tion demonstrating that each batch in each shipment
22 offered for importation into the United States was sta-
23 tistically sampled and tested for authenticity and deg-
24 radation.

25 “(K) Certification from the importer or manufac-
26 turer of the prescription drug that the prescription
27 drug—

28 “(i) is approved for marketing in the United
29 States; and

30 “(ii) meets all labeling requirements under this
31 Act.

32 “(L) Laboratory records, including complete data
33 derived from all tests necessary to ensure that the pre-
34 scription drug is in compliance with established speci-
35 fications and standards.



1 “(M) Documentation demonstrating that the test-
2 ing required by subparagraphs (J) and (L) was con-
3 ducted at a qualifying laboratory.

4 “(N) Any other information that the Secretary de-
5 termines is necessary to ensure the protection of the
6 public health.

7 “(2) MAINTENANCE BY THE SECRETARY.—The Sec-
8 retary shall maintain information and documentation sub-
9 mitted under paragraph (1) for such period of time as the
10 Secretary determines to be necessary.

11 “(e) TESTING.—The regulations under subsection (b) shall
12 require—

13 “(1) that testing described in subparagraphs (J) and
14 (L) of subsection (d)(1) be conducted by the importer or
15 by the manufacturer of the prescription drug at a qualified
16 laboratory;

17 “(2) if the tests are conducted by the importer—

18 “(A) that information needed to—

19 “(i) authenticate the prescription drug being
20 tested; and

21 “(ii) confirm that the labeling of the prescrip-
22 tion drug complies with labeling requirements
23 under this Act;

24 be supplied by the manufacturer of the prescription
25 drug to the pharmacist or wholesaler; and

26 “(B) that the information supplied under subpara-
27 graph (A) be kept in strict confidence and used only for
28 purposes of testing or otherwise complying with this
29 Act; and

30 “(3) may include such additional provisions as the
31 Secretary determines to be appropriate to provide for the
32 protection of trade secrets and commercial or financial in-
33 formation that is privileged or confidential.

34 “(f) REGISTRATION OF FOREIGN SELLERS.—Any estab-
35 lishment within Canada engaged in the distribution of a pre-
36 scription drug that is imported or offered for importation into



1 the United States shall register with the Secretary the name
2 and place of business of the establishment.

3 “(g) SUSPENSION OF IMPORTATION.—The Secretary shall
4 require that importations of a specific prescription drug or im-
5 portations by a specific importer under subsection (b) be imme-
6 diately suspended on discovery of a pattern of importation of
7 that specific prescription drug or by that specific importer of
8 drugs that are counterfeit or in violation of any requirement
9 under this section, until an investigation is completed and the
10 Secretary determines that the public is adequately protected
11 from counterfeit and violative prescription drugs being im-
12 ported under subsection (b).

13 “(h) APPROVED LABELING.—The manufacturer of a pre-
14 scription drug shall provide an importer written authorization
15 for the importer to use, at no cost, the approved labeling for
16 the prescription drug.

17 “(i) PROHIBITION OF DISCRIMINATION.—

18 “(1) IN GENERAL.—It shall be unlawful for a manu-
19 facturer of a prescription drug to discriminate against, or
20 cause any other person to discriminate against, a phar-
21 macist or wholesaler that purchases or offers to purchase
22 a prescription drug from the manufacturer or from any
23 person that distributes a prescription drug manufactured
24 by the drug manufacturer.

25 “(2) DISCRIMINATION.—For the purposes of para-
26 graph (1), a manufacturer of a prescription drug shall be
27 considered to discriminate against a pharmacist or whole-
28 saler if the manufacturer enters into a contract for sale of
29 a prescription drug, places a limit on supply, or employs
30 any other measure, that has the effect of—

31 “(A) providing pharmacists or wholesalers access
32 to prescription drugs on terms or conditions that are
33 less favorable than the terms or conditions provided to
34 a foreign purchaser (other than a charitable or humani-
35 tarian organization) of the prescription drug; or



1 “(B) restricting the access of pharmacists or
2 wholesalers to a prescription drug that is permitted to
3 be imported into the United States under this section.

4 “(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any
5 other provision of this section, section 801(d)(1) continues to
6 apply to a prescription drug that is donated or otherwise sup-
7 plied at no charge by the manufacturer of the drug to a chari-
8 table or humanitarian organization (including the United Na-
9 tions and affiliates) or to a government of a foreign country.

10 “(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVID-
11 UALS.—

12 “(1) DECLARATIONS.—Congress declares that in the
13 enforcement against individuals of the prohibition of impor-
14 tation of prescription drugs and devices, the Secretary
15 should—

16 “(A) focus enforcement on cases in which the im-
17 portation by an individual poses a significant threat to
18 public health; and

19 “(B) exercise discretion to permit individuals to
20 make such importations in circumstances in which—

21 “(i) the importation is clearly for personal use;
22 and

23 “(ii) the prescription drug or device imported
24 does not appear to present an unreasonable risk to
25 the individual.

26 “(2) WAIVER AUTHORITY.—

27 “(A) IN GENERAL.—The Secretary may grant to
28 individuals, by regulation or on a case-by-case basis, a
29 waiver of the prohibition of importation of a prescrip-
30 tion drug or device or class of prescription drugs or de-
31 vices, under such conditions as the Secretary deter-
32 mines to be appropriate.

33 “(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The
34 Secretary shall publish, and update as necessary, guid-
35 ance that accurately describes circumstances in which
36 the Secretary will consistently grant waivers on a case-
37 by-case basis under subparagraph (A), so that individ-



1 uals may know with the greatest practicable degree of
2 certainty whether a particular importation for personal
3 use will be permitted.

4 “(3) DRUGS IMPORTED FROM CANADA.—In particular,
5 the Secretary shall by regulation grant individuals a waiver
6 to permit individuals to import into the United States a
7 prescription drug that—

8 “(A) is imported from a licensed pharmacy for
9 personal use by an individual, not for resale, in quan-
10 tities that do not exceed a 90-day supply;

11 “(B) is accompanied by a copy of a valid prescrip-
12 tion;

13 “(C) is imported from Canada, from a seller reg-
14 istered with the Secretary;

15 “(D) is a prescription drug approved by the Sec-
16 retary under chapter V;

17 “(E) is in the form of a final finished dosage that
18 was manufactured in an establishment registered under
19 section 510; and

20 “(F) is imported under such other conditions as
21 the Secretary determines to be necessary to ensure
22 public safety.

23 “(I) STUDIES; REPORTS.—

24 “(1) BY THE INSTITUTE OF MEDICINE OF THE NA-
25 TIONAL ACADEMY OF SCIENCES.—

26 “(A) STUDY.—

27 “(i) IN GENERAL.—The Secretary shall re-
28 quest that the Institute of Medicine of the National
29 Academy of Sciences conduct a study of—

30 “(I) importations of prescription drugs
31 made under the regulations under subsection
32 (b); and

33 “(II) information and documentation sub-
34 mitted under subsection (d).

35 “(ii) REQUIREMENTS.—In conducting the
36 study, the Institute of Medicine shall—



1 “(I) evaluate the compliance of importers
2 with the regulations under subsection (b);

3 “(II) compare the number of shipments
4 under the regulations under subsection (b) dur-
5 ing the study period that are determined to be
6 counterfeit, misbranded, or adulterated, and
7 compare that number with the number of ship-
8 ments made during the study period within the
9 United States that are determined to be coun-
10 terfeit, misbranded, or adulterated; and

11 “(III) consult with the Secretary, the
12 United States Trade Representative, and the
13 Commissioner of Patents and Trademarks to
14 evaluate the effect of importations under the
15 regulations under subsection (b) on trade and
16 patent rights under Federal law.

17 “(B) REPORT.—Not later than 2 years after the
18 effective date of the regulations under subsection (b),
19 the Institute of Medicine shall submit to Congress a re-
20 port describing the findings of the study under sub-
21 paragraph (A).

22 “(2) BY THE COMPTROLLER GENERAL.—

23 “(A) STUDY.—The Comptroller General of the
24 United States shall conduct a study to determine the
25 effect of this section on the price of prescription drugs
26 sold to consumers at retail.

27 “(B) REPORT.—Not later than 18 months after
28 the effective date of the regulations under subsection
29 (b), the Comptroller General of the United States shall
30 submit to Congress a report describing the findings of
31 the study under subparagraph (A).

32 “(m) CONSTRUCTION.—Nothing in this section limits the
33 authority of the Secretary relating to the importation of pre-
34 scription drugs, other than with respect to section 801(d)(1) as
35 provided in this section.

36 “(n) EFFECTIVENESS OF SECTION.—



1 “(1) IN GENERAL.—If, after the date that is 1 year
2 after the effective date of the regulations under subsection
3 (b) and before the date that is 18 months after the effec-
4 tive date, the Secretary submits to Congress a certification
5 that, in the opinion of the Secretary, based on substantial
6 evidence obtained after the effective date, the benefits of
7 implementation of this section do not outweigh any det-
8 riment of implementation of this section, this section shall
9 cease to be effective as of the date that is 30 days after
10 the date on which the Secretary submits the certification.

11 “(2) PROCEDURE.—The Secretary shall not submit a
12 certification under paragraph (1) unless, after a hearing on
13 the record under sections 556 and 557 of title 5, United
14 States Code, the Secretary—

15 “(A)(i) determines that it is more likely than not
16 that implementation of this section would result in an
17 increase in the risk to the public health and safety;

18 “(ii) identifies specifically, in qualitative and quan-
19 titative terms, the nature of the increased risk;

20 “(iii) identifies specifically the causes of the in-
21 creased risk; and

22 “(iv)(I) considers whether any measures can be
23 taken to avoid, reduce, or mitigate the increased risk;
24 and

25 “(II) if the Secretary determines that any meas-
26 ures described in subclause (I) would require additional
27 statutory authority, submits to Congress a report de-
28 scribing the legislation that would be required;

29 “(B) identifies specifically, in qualitative and
30 quantitative terms, the benefits that would result from
31 implementation of this section (including the benefit of
32 reductions in the cost of covered products to consumers
33 in the United States, allowing consumers to procure
34 needed medication that consumers might not otherwise
35 be able to procure without foregoing other necessities
36 of life); and



1 “(C)(i) compares in specific terms the detriment
2 identified under subparagraph (A) with the benefits
3 identified under subparagraph (B); and

4 “(ii) determines that the benefits do not outweigh
5 the detriment.

6 “(o) AUTHORIZATION OF APPROPRIATIONS.—There are
7 authorized to be appropriated such sums as are necessary to
8 carry out this section.

9 “(p) CONDITIONS.—This section shall become effective
10 only if the Secretary certifies to the Congress that implementa-
11 tion of this section will—

12 “(1) pose no additional risk to the public’s health and
13 safety; and

14 “(2) result in a significant reduction in the cost of
15 covered products to the American consumer.”.

16 (b) CONFORMING AMENDMENTS.—The Federal Food,
17 Drug, and Cosmetic Act is amended—

18 (1) in section 301(aa) (21 U.S.C. 331(aa)), by striking
19 “covered product in violation of section 804” and inserting
20 “prescription drug in violation of section 804”; and

21 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6)), by
22 striking “covered product pursuant to section 804(a)” and
23 inserting “prescription drug under section 804(b)”.

24 **TITLE XI—ACCESS TO**
25 **AFFORDABLE PHARMACEUTICALS**

26 **SEC. 1101. SHORT TITLE.**

27 This title may be cited as the “Greater Access to Afford-
28 able Pharmaceuticals Act”.

29 **SEC. 1102. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

30 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Section
31 505(j) of the Federal Food, Drug, and Cosmetic Act (21
32 U.S.C. 355(j)) is amended—

33 (1) in paragraph (2), by striking subparagraph (B)
34 and inserting the following:

35 “(B) NOTICE OF OPINION THAT PATENT IS INVALID OR
36 WILL NOT BE INFRINGED.—



1 “(i) AGREEMENT TO GIVE NOTICE.—An applicant that
2 makes a certification described in subparagraph
3 (A)(vii)(IV) shall include in the application a statement
4 that the applicant will give notice as required by this sub-
5 paragraph.

6 “(ii) TIMING OF NOTICE.—An applicant that makes a
7 certification described in subparagraph (A)(vii)(IV) shall
8 give notice as required under this subparagraph—

9 “(I) if the certification is in the application, not
10 later than 20 days after the date of the postmark on
11 the notice with which the Secretary informs the appli-
12 cant that the application has been filed; or

13 “(II) if the certification is in an amendment or
14 supplement to the application, at the time at which the
15 applicant submits the amendment or supplement, re-
16 gardless of whether the applicant has already given no-
17 tice with respect to another such certification contained
18 in the application or in an amendment or supplement
19 to the application.

20 “(iii) RECIPIENTS OF NOTICE.—An applicant required
21 under this subparagraph to give notice shall give notice
22 to—

23 “(I) each owner of the patent that is the subject
24 of the certification (or a representative of the owner
25 designated to receive such a notice); and

26 “(II) the holder of the approved application under
27 subsection (b) for the drug that is claimed by the pat-
28 ent or a use of which is claimed by the patent (or a
29 representative of the holder designated to receive such
30 a notice).

31 “(iv) CONTENTS OF NOTICE.—A notice required under
32 this subparagraph shall—

33 “(I) state that an application that contains data
34 from bioavailability or bioequivalence studies has been
35 submitted under this subsection for the drug with re-
36 spect to which the certification is made to obtain ap-
37 proval to engage in the commercial manufacture, use,



1 or sale of the drug before the expiration of the patent
2 referred to in the certification; and

3 “(II) include a detailed statement of the factual
4 and legal basis of the opinion of the applicant that the
5 patent is invalid or will not be infringed.”; and

6 (2) in paragraph (5)—

7 (A) in subparagraph (B)—

8 (i) by striking “under the following” and in-
9 serting “by applying the following to each certifi-
10 cation made under paragraph (2)(A)(vii)”;

11 (ii) in clause (iii)—

12 (I) in the first sentence, by striking “un-
13 less” and all that follows and inserting “unless,
14 before the expiration of 45 days after the date
15 on which the notice described in paragraph
16 (2)(B) is received, an action is brought for in-
17 fringement of the patent that is the subject of
18 the certification and for which information was
19 submitted to the Secretary under subsection
20 (b)(1) or (c)(2) before the date on which the
21 application (excluding an amendment or sup-
22 plement to the application), which the Sec-
23 retary later determines to be substantially com-
24 plete, was submitted.”; and

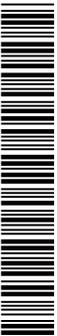
25 (II) in the second sentence—

26 (aa) by striking subclause (I) and in-
27 serting the following:

28 “(I) if before the expiration of such period the dis-
29 trict court decides that the patent is invalid or not in-
30 fringed (including any substantive determination that
31 there is no cause of action for patent infringement or
32 invalidity), the approval shall be made effective on—

33 “(aa) the date on which the court enters judg-
34 ment reflecting the decision; or

35 “(bb) the date of a settlement order or consent
36 decree signed and entered by the court stating that



1 the patent that is the subject of the certification is
2 invalid or not infringed;”;

3 (bb) by striking subclause (II) and in-
4 serting the following:

5 “(II) if before the expiration of such period the
6 district court decides that the patent has been
7 infringed—

8 “(aa) if the judgment of the district court is
9 appealed, the approval shall be made effective on—

10 “(AA) the date on which the court of ap-
11 peals decides that the patent is invalid or not
12 infringed (including any substantive determina-
13 tion that there is no cause of action for patent
14 infringement or invalidity); or

15 “(BB) the date of a settlement order or
16 consent decree signed and entered by the court
17 of appeals stating that the patent that is the
18 subject of the certification is invalid or not in-
19 fringed; or

20 “(bb) if the judgment of the district court is
21 not appealed or is affirmed, the approval shall be
22 made effective on the date specified by the district
23 court in a court order under section 271(e)(4)(A)
24 of title 35, United States Code;”;

25 (cc) in subclause (III), by striking “on
26 the date of such court decision.” and in-
27 serting “as provided in subclause (I); or”;
28 and

29 (dd) by inserting after subclause (III)
30 the following:

31 “(IV) if before the expiration of such period the
32 court grants a preliminary injunction prohibiting the
33 applicant from engaging in the commercial manufac-
34 ture or sale of the drug until the court decides the
35 issues of patent validity and infringement and if the
36 court decides that such patent has been infringed, the



1 approval shall be made effective as provided in sub-
2 clause (II).”;

3 (B) by redesignating subparagraphs (C) and (D)
4 as subparagraphs (E) and (F), respectively; and

5 (C) by inserting after subparagraph (B) the fol-
6 lowing:

7 “(C) CIVIL ACTION TO OBTAIN PATENT CER-
8 TAINTY.—

9 “(i) DECLARATORY JUDGMENT ABSENT IN-
10 FRINGEMENT ACTION.—If an owner of the patent
11 or the holder of the approved application under
12 subsection (b) for the drug that is claimed by the
13 patent or a use of which is claimed by the patent
14 does not bring a civil action against the applicant
15 for infringement of the patent on or before the date
16 that is 45 days after the date on which the notice
17 given under paragraph (2)(B) was received, the ap-
18 plicant may bring a civil action against the owner
19 or holder (but not against any owner or holder that
20 has brought such a civil action against that appli-
21 cant, unless that civil action was dismissed without
22 prejudice) for a declaratory judgment under section
23 2201 of title 28, United States Code, that the pat-
24 ent is invalid or will not be infringed by the drug
25 for which the applicant seeks approval.

26 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-
27 TION.—

28 “(I) IN GENERAL.—If an owner of the
29 patent or the holder of the approved applica-
30 tion under subsection (b) for the drug that is
31 claimed by the patent or a use of which is
32 claimed by the patent brings a patent infringe-
33 ment action against the applicant, the appli-
34 cant may assert a counterclaim seeking an
35 order requiring the holder to correct or delete
36 the patent information submitted by the holder



1 under subsection (b) or (c) on the ground that
2 the patent does not claim either—

3 “(aa) the drug for which the applica-
4 tion was approved; or

5 “(bb) an approved method of using
6 the drug.

7 “(II) NO INDEPENDENT CAUSE OF AC-
8 TION.—Subclause (I) does not authorize the as-
9 sertion of a claim described in subclause (I) in
10 any civil action or proceeding other than a
11 counterclaim described in subclause (I).

12 “(iii) NO DAMAGES.—An applicant shall not
13 be entitled to damages in a civil action under sub-
14 paragraph (i) or a counterclaim under subpara-
15 graph (ii).”.

16 (b) APPLICATIONS GENERALLY.—Section 505 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) is
18 amended—

19 (1) in subsection (b), by striking paragraph (3) and
20 inserting the following:

21 “(3) NOTICE OF OPINION THAT PATENT IS INVALID OR
22 WILL NOT BE INFRINGED.—

23 “(A) AGREEMENT TO GIVE NOTICE.—An applicant
24 that makes a certification described in paragraph (2)(A)(iv)
25 shall include in the application a statement that the appli-
26 cant will give notice as required by this paragraph.

27 “(B) TIMING OF NOTICE.—An applicant that makes a
28 certification described in paragraph (2)(A)(iv) shall give
29 notice as required under this paragraph—

30 “(i) if the certification is in the application, not
31 later than 20 days after the date of the postmark on
32 the notice with which the Secretary informs the appli-
33 cant that the application has been filed; or

34 “(ii) if the certification is in an amendment or
35 supplement to the application, at the time at which the
36 applicant submits the amendment or supplement, re-
37 gardless of whether the applicant has already given no-



1 tice with respect to another such certification contained
2 in the application or in an amendment or supplement
3 to the application.

4 “(C) RECIPIENTS OF NOTICE.—An applicant required
5 under this paragraph to give notice shall give notice to—

6 “(i) each owner of the patent that is the subject
7 of the certification (or a representative of the owner
8 designated to receive such a notice); and

9 “(ii) the holder of the approved application under
10 this subsection for the drug that is claimed by the pat-
11 ent or a use of which is claimed by the patent (or a
12 representative of the holder designated to receive such
13 a notice).

14 “(D) CONTENTS OF NOTICE.—A notice required under
15 this paragraph shall—

16 “(i) state that an application that contains data
17 from bioavailability or bioequivalence studies has been
18 submitted under this subsection for the drug with re-
19 spect to which the certification is made to obtain ap-
20 proval to engage in the commercial manufacture, use,
21 or sale of the drug before the expiration of the patent
22 referred to in the certification; and

23 “(ii) include a detailed statement of the factual
24 and legal basis of the opinion of the applicant that the
25 patent is invalid or will not be infringed.”; and

26 (2) in subsection (c)(3)—

27 (A) in the first sentence, by striking “under the
28 following” and inserting “by applying the following to
29 each certification made under subsection (b)(2)(A)(iv)”;

30 (B) in subparagraph (C)—

31 (i) in the first sentence, by striking “unless”
32 and all that follows and inserting “unless, before
33 the expiration of 45 days after the date on which
34 the notice described in subsection (b)(3) is received,
35 an action is brought for infringement of the patent
36 that is the subject of the certification and for which
37 information was submitted to the Secretary under



1 paragraph (2) or subsection (b)(1) before the date
2 on which the application (excluding an amendment
3 or supplement to the application) was submitted.”;

4 (ii) in the second sentence—

5 (I) by striking “paragraph (3)(B)” and in-
6 serting “subsection (b)(3)”;

7 (II) by striking clause (i) and inserting the
8 following:

9 “(i) if before the expiration of such period the dis-
10 trict court decides that the patent is invalid or not in-
11 fringed (including any substantive determination that
12 there is no cause of action for patent infringement or
13 invalidity), the approval shall be made effective on—

14 “(I) the date on which the court enters judg-
15 ment reflecting the decision; or

16 “(II) the date of a settlement order or consent
17 decree signed and entered by the court stating that
18 the patent that is the subject of the certification is
19 invalid or not infringed;”;

20 (III) by striking clause (ii) and inserting
21 the following:

22 “(ii) if before the expiration of such period the dis-
23 trict court decides that the patent has been infringed—

24 “(I) if the judgment of the district court is ap-
25 pealed, the approval shall be made effective on—

26 “(aa) the date on which the court of ap-
27 peals decides that the patent is invalid or not
28 infringed (including any substantive determina-
29 tion that there is no cause of action for patent
30 infringement or invalidity); or

31 “(bb) the date of a settlement order or
32 consent decree signed and entered by the court
33 of appeals stating that the patent that is the
34 subject of the certification is invalid or not in-
35 fringed; or

36 “(II) if the judgment of the district court is
37 not appealed or is affirmed, the approval shall be



1 made effective on the date specified by the district
2 court in a court order under section 271(e)(4)(A)
3 of title 35, United States Code;”;

4 (IV) in clause (iii), by striking “on the
5 date of such court decision.” and inserting “as
6 provided in clause (i); or”; and

7 (V) by inserting after clause (iii), the fol-
8 lowing:

9 “(iv) if before the expiration of such period the
10 court grants a preliminary injunction prohibiting the
11 applicant from engaging in the commercial manufac-
12 ture or sale of the drug until the court decides the
13 issues of patent validity and infringement and if the
14 court decides that such patent has been infringed, the
15 approval shall be made effective as provided in clause
16 (ii).”; and

17 (iii) in the third sentence, by striking “para-
18 graph (3)(B)” and inserting “subsection (b)(3)”;

19 (C) by redesignating subparagraph (D) as sub-
20 paragraph (E); and

21 (D) by inserting after subparagraph (C) the fol-
22 lowing:

23 “(D) CIVIL ACTION TO OBTAIN PATENT CER-
24 TAINTY.—

25 “(i) DECLARATORY JUDGMENT ABSENT IN-
26 FRINGEMENT ACTION.—If an owner of the patent
27 or the holder of the approved application under
28 subsection (b) for the drug that is claimed by the
29 patent or a use of which is claimed by the patent
30 does not bring a civil action against the applicant
31 for infringement of the patent on or before the date
32 that is 45 days after the date on which the notice
33 given under subsection (b)(3) was received, the ap-
34 plicant may bring a civil action against the owner
35 or holder (but not against any owner or holder that
36 has brought such a civil action against that appli-
37 cant, unless that civil action was dismissed without



1 prejudice) for a declaratory judgment under section
2 2201 of title 28, United States Code, that the pat-
3 ent is invalid or will not be infringed by the drug
4 for which the applicant seeks approval.

5 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-
6 TION.—

7 “(I) IN GENERAL.—If an owner of the
8 patent or the holder of the approved applica-
9 tion under subsection (b) for the drug that is
10 claimed by the patent or a use of which is
11 claimed by the patent brings a patent infringe-
12 ment action against the applicant, the appli-
13 cant may assert a counterclaim seeking an
14 order requiring the holder to correct or delete
15 the patent information submitted by the holder
16 under subsection (b) or this subsection on the
17 ground that the patent does not claim either—

18 “(aa) the drug for which the applica-
19 tion was approved; or

20 “(bb) an approved method of using
21 the drug.

22 “(II) NO INDEPENDENT CAUSE OF AC-
23 TION.—Subclause (I) does not authorize the as-
24 sertion of a claim described in subclause (I) in
25 any civil action or proceeding other than a
26 counterclaim described in subclause (I).

27 “(iii) NO DAMAGES.—An applicant shall not
28 be entitled to damages in a civil action under
29 clause (i) or a counterclaim under clause (ii).”.

30 (c) INFRINGEMENT ACTIONS.—Section 271(e) of title 35,
31 United States Code, is amended by adding at the end the fol-
32 lowing:

33 “(5) The filing of an application described in para-
34 graph (2) that includes a certification under subsection
35 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the
36 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355),
37 and the failure of the owner of the patent to bring an ac-



1 tion for infringement of a patent that is the subject of the
2 certification before the expiration of 45 days after the date
3 on which the notice given under subsection (b)(3) or
4 (j)(2)(B) of that section is received, shall establish an ac-
5 tual controversy between the applicant and the patent
6 owner sufficient to confer subject matter jurisdiction in the
7 courts of the United States in any action brought by the
8 applicant under section 2201 of title 28 for a declaratory
9 judgment that any patent that is the subject of the certifi-
10 cation is invalid or not infringed.”.

11 (d) APPLICABILITY.—

12 (1) IN GENERAL.—Except as provided in paragraphs
13 (2) and (3), the amendments made by subsections (a), (b),
14 and (c) apply to any proceeding under section 505 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
16 that is pending on or after the date of enactment of this
17 Act regardless of the date on which the proceeding was
18 commenced or is commenced.

19 (2) NOTICE OF OPINION THAT PATENT IS INVALID OR
20 WILL NOT BE INFRINGED.—The amendments made by sub-
21 sections (a)(1) and (b)(1) apply with respect to any certifi-
22 cation under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)
23 of section 505 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 355) after the date of enactment of this Act
25 in an application filed under subsection (b)(2) or (j) of that
26 section or in an amendment or supplement to an applica-
27 tion filed under subsection (b)(2) or (j) of that section.

28 (3) EFFECTIVE DATE OF APPROVAL.—The amend-
29 ments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i)
30 apply with respect to any patent information submitted
31 under subsection (b)(1) or (c)(2) of section 505 of the Fed-
32 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) made
33 after the date of enactment of this Act.



1 **SEC. 1103. FORFEITURE OF 180-DAY EXCLUSIVITY PE-**
2 **RIOD.**

3 (a) IN GENERAL.—Section 505(j)(5) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by
5 section 1102) is amended—

6 (1) in subparagraph (B), by striking clause (iv) and
7 inserting the following:

8 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

9 “(I) DEFINITIONS.—In this paragraph:

10 “(aa) 180-DAY EXCLUSIVITY PERIOD.—The
11 term ‘180-day exclusivity period’ means the 180-
12 day period ending on the day before the date on
13 which an application submitted by an applicant
14 other than a first applicant could become effective
15 under this clause.

16 “(bb) FIRST APPLICANT.—The term ‘first ap-
17 plicant’ means an applicant that, on the first day
18 on which a substantially complete application con-
19 taining a certification described in paragraph
20 (2)(A)(vii)(IV) is submitted for approval of a drug,
21 submits a substantially complete application con-
22 taining a certification described in paragraph
23 (2)(A)(vii)(IV) for the drug.

24 “(cc) SUBSTANTIALLY COMPLETE APPLICA-
25 TION.—The term ‘substantially complete applica-
26 tion’ means an application under this subsection
27 that on its face is sufficiently complete to permit
28 a substantive review and contains all the informa-
29 tion required by paragraph (2)(A).

30 “(dd) TENTATIVE APPROVAL.—

31 “(AA) IN GENERAL.—The term ‘tentative
32 approval’ means notification to an applicant by
33 the Secretary that an application under this
34 subsection meets the requirements of para-
35 graph (2)(A), but cannot receive effective ap-
36 proval because the application does not meet
37 the requirements of this subparagraph, there is



1 a period of exclusivity for the listed drug under
2 subparagraph (E) or section 505A, or there is
3 a 7-year period of exclusivity for the listed drug
4 under section 527.

5 “(BB) LIMITATION.—A drug that is
6 granted tentative approval by the Secretary is
7 not an approved drug and shall not have an ef-
8 fective approval until the Secretary issues an
9 approval after any necessary additional review
10 of the application.

11 “(II) EFFECTIVENESS OF APPLICATION.—Subject
12 to subparagraph (D), if the application contains a cer-
13 tification described in paragraph (2)(A)(vii)(IV) and is
14 for a drug for which a first applicant has submitted an
15 application containing such a certification, the applica-
16 tion shall be made effective on the date that is 180
17 days after the date of the first commercial marketing
18 of the drug (including the commercial marketing of the
19 listed drug) by any first applicant.”; and

20 (2) by inserting after subparagraph (C) the following:

21 “(D) FORFEITURE OF 180-DAY EXCLUSIVITY PE-
22 RIOD.—

23 “(i) DEFINITION OF FORFEITURE EVENT.—In
24 this subparagraph, the term ‘forfeiture event’, with
25 respect to an application under this subsection,
26 means the occurrence of any of the following:

27 “(I) FAILURE TO MARKET.—The first ap-
28 plicant fails to market the drug by the later
29 of—

30 “(aa) the earlier of the date that is—

31 “(AA) 75 days after the date on
32 which the approval of the application of
33 the first applicant is made effective
34 under subparagraph (B)(iii); or

35 “(BB) 30 months after the date of
36 submission of the application of the
37 first applicant; or



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“(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

“(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

“(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

“(CC) The patent expires.

“(DD) The patent is withdrawn by the holder of the application approved under subsection (b).

“(II) WITHDRAWAL OF APPLICATION.—
The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application



1 does not meet the requirements for approval
2 under paragraph (4).

3 “(III) AMENDMENT OF CERTIFICATION.—
4 The first applicant amends or withdraws the
5 certification for all of the patents with respect
6 to which that applicant submitted a certifi-
7 cation qualifying the applicant for the 180-day
8 exclusivity period.

9 “(IV) FAILURE TO OBTAIN TENTATIVE AP-
10 PROVAL.—The first applicant fails to obtain
11 tentative approval of the application within 30
12 months after the date on which the application
13 is filed, unless the failure is caused by a change
14 in or a review of the requirements for approval
15 of the application imposed after the date on
16 which the application is filed.

17 “(V) AGREEMENT WITH ANOTHER APPLI-
18 CANT, THE LISTED DRUG APPLICATION HOLD-
19 ER, OR A PATENT OWNER.—The first applicant
20 enters into an agreement with another appli-
21 cant under this subsection for the drug, the
22 holder of the application for the listed drug, or
23 an owner of the patent that is the subject of
24 the certification under paragraph
25 (2)(A)(vii)(IV), the Federal Trade Commission
26 or the Attorney General files a complaint, and
27 there is a final decision of the Federal Trade
28 Commission or the court with regard to the
29 complaint from which no appeal (other than a
30 petition to the Supreme Court for a writ of cer-
31 tiorari) has been or can be taken that the
32 agreement has violated the antitrust laws (as
33 defined in section 1 of the Clayton Act (15
34 U.S.C. 12), except that the term includes sec-
35 tion 5 of the Federal Trade Commission Act
36 (15 U.S.C. 45) to the extent that that section
37 applies to unfair methods of competition).



1 “(VI) EXPIRATION OF ALL PATENTS.—All
2 of the patents as to which the applicant sub-
3 mitted a certification qualifying it for the 180-
4 day exclusivity period have expired.

5 “(ii) FORFEITURE.—The 180-day exclusivity
6 period described in subparagraph (B)(iv) shall be
7 forfeited by a first applicant if a forfeiture event
8 occurs with respect to that first applicant.

9 “(iii) SUBSEQUENT APPLICANT.—If all first
10 applicants forfeit the 180-day exclusivity period
11 under clause (ii)—

12 “(I) approval of any application containing
13 a certification described in paragraph
14 (2)(A)(vii)(IV) shall be made effective in ac-
15 cordance with subparagraph (B)(iii); and

16 “(II) no applicant shall be eligible for a
17 180-day exclusivity period.”.

18 (b) EFFECTIVE DATE.—

19 (1) IN GENERAL.—Except as provided in paragraph
20 (2), the amendment made by subsection (a) shall be effec-
21 tive only with respect to an application filed under section
22 505(j) of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 355(j)) after the date of enactment of this Act for
24 a listed drug for which no certification under section
25 505(j)(2)(A)(vii)(IV) of that Act was made before the date
26 of enactment of this Act.

27 (2) COLLUSIVE AGREEMENTS.—If a forfeiture event
28 described in section 505(j)(5)(D)(i)(V) of that Act occurs
29 in the case of an applicant, the applicant shall forfeit the
30 180-day period under section 505(j)(5)(B)(iv) of that Act
31 without regard to when the first certification under section
32 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was
33 made.

34 (3) DECISION OF A COURT WHEN THE 180-DAY EXCLU-
35 SIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect
36 to an application filed before, on, or after the date of enact-
37 ment of this Act for a listed drug for which a certification



1 under section 505(j)(2)(A)(vii)(IV) of that Act was made
2 before the date of enactment of this Act and for which nei-
3 ther of the events described in subclause (I) or (II) of sec-
4 tion 505(j)(5)(B)(iv) of that Act (as in effect on the day
5 before the date of enactment of this Act) has occurred on
6 or before the date of enactment of this Act, the term “deci-
7 sion of a court” as used in clause (iv) of section
8 505(j)(5)(B) of that Act means a final decision of a court
9 from which no appeal (other than a petition to the Su-
10 preme Court for a writ of certiorari) has been or can be
11 taken.

12 **SEC. 1104. BIOAVAILABILITY AND BIOEQUIVALENCE.**

13 (a) IN GENERAL.—Section 505(j)(8) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

15 (1) by striking subparagraph (A) and inserting the fol-
16 lowing:

17 “(A)(i) The term ‘bioavailability’ means the rate and
18 extent to which the active ingredient or therapeutic ingre-
19 dient is absorbed from a drug and becomes available at the
20 site of drug action.

21 “(ii) For a drug that is not intended to be absorbed
22 into the bloodstream, the Secretary may assess bio-
23 availability by scientifically valid measurements intended to
24 reflect the rate and extent to which the active ingredient
25 or therapeutic ingredient becomes available at the site of
26 drug action.”; and

27 (2) by adding at the end the following:

28 “(C) For a drug that is not intended to be absorbed
29 into the bloodstream, the Secretary may establish alter-
30 native, scientifically valid methods to show bioequivalence if
31 the alternative methods are expected to detect a significant
32 difference between the drug and the listed drug in safety
33 and therapeutic effect.”.

34 (b) EFFECT OF AMENDMENT.—The amendment made by
35 subsection (a) does not alter the standards for approval of
36 drugs under section 505(j) of the Federal Food, Drug, and
37 Cosmetic Act (21 U.S.C. 355(j)).



1 **SEC. 1105. REMEDIES FOR INFRINGEMENT.**

2 Section 287 of title 35, United States Code, is amended
3 by adding at the end the following:

4 “(d) CONSIDERATION.—In making a determination with
5 respect to remedy brought for infringement of a patent that
6 claims a drug or a method or using a drug, the court shall con-
7 sider whether information on the patent was filed as required
8 under 21 U.S.C. 355 (b) or (c), and, if such information was
9 required to be filed but was not, the court may refuse to award
10 treble damages under section 284.”.

11 **SEC. 1106. CONFORMING AMENDMENTS.**

12 Section 505A of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 355a) is amended—

14 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by
15 striking “(j)(5)(D)(ii)” each place it appears and inserting
16 “(j)(5)(F)(ii)”;

17 (2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by
18 striking “(j)(5)(D)” each place it appears and inserting
19 “(j)(5)(F)”;

20 (3) in subsections (e) and (l), by striking
21 “505(j)(5)(D)” each place it appears and inserting
22 “505(j)(5)(F)”.

